Title Page

Ethical and Governance Challenges in Population Biobanking: the case of the global Anti-Doping Administration & Management System

by

Rachel Catherine Thompson

Submitted to Swansea University in fulfilment of the requirements for the Degree of

Doctor of Philosophy

Swansea University

2021

Abstract

This study is an ethical analysis of the governance and regulatory dimensions of biobanking with specific reference to the Anti-Doping Administration Management System (ADAMS) of the global regulator of anti-doping in sports, the World Anti-Doping Agency (WADA). The study focuses on four key ethico-governance issues: (i) consent; (ii) benefit-sharing; (iii) harmonization of ethics and governance; and (iv) conditions for the secondary research uses of data originally collected for doping control purposes.

It is argued that the consent process prior to data collection, storage and analysis is problematic, since athletes may not refuse the request to provide data sought by anti-doping authorities without forfeiting their eligibility to compete. The process requires simultaneous permission for research and testing which creates ambiguity, compounded by the unequal relationship between athletes and WADA. A range of alternative models are explored and a case is made for an approach that combines broad consent with iterative, or 'reflexive' governance and stakeholder involvement including education around research.

Furthermore, ethical issues remain concerning governance and regulation for population research and use of data more generally between legal jurisdictions and within diverse populations. It is also argued that WADA's claim to harmonization through its operational methods, regulation and governance, is not sufficiently well-defined outside of specific legal uses and is therefore too blunt a tool for ethical governance in global sport contexts.

This thesis proposes reforms to existing WADA processes including consent processes and moves toward more reflexive governance frameworks that allow contextual nuance and iterative development, respecting differing needs within a shared structure. Specific recommendations are made to enhance accountability for potential secondary uses of ADAMS data for research. A distinction is drawn between anti-doping and broader biomedical research in developing ethically justifiable pathways that reduce the potential for coercion and empower athletes as contributors and potential beneficiaries.

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Declaration

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Declarations

This work has not previously been accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

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Publications

Chapter 4 on Consent is partly based on work previously published as Sheehan, M., Thompson, R., Davies, J., Dunn, M., Fistein, J., Parker, M., Savulescu, J. & Woods, K. (2019) and the future of consent: Authority and consent in population-scale biomedical research. *Public Health Ethics*.

And Thompson, R., & McNamee, M. J. (2017). Consent, ethics and genetic biobanks: the case of the Athlome project. *BMC Genomics*, 18(Suppl 8), 830. doi:10.1186/s12864-017-4189-1

For Sheehan et al (2019) I was the second and corresponding author- Dr Sheehan and I co-conceived the paper and wrote the first draft based on a meeting of the author group, I co-edited subsequent drafts and managed submission and revisions.

For Thompson& McNamee (2017) I was first and corresponding author and co-wrote all drafts of the paper with Prof McNamee.

Acronyms and Abbreviations

ADAMS Anti-Doping Administration and Management System

ABP Athlete Biological Passport

ADO Anti-Doping Organization

CAS Court of Arbitration for Sport

CE Council of Europe

CEU Council of the European Union

CJEU Court of Justice of the European Union

DPA 1998 Data Protection Act 1998

DPA 2018 Data Protection 2018

ECHR European Convention on Human Rights

ECJ European Court of Justice

ECtHR European Court of Human Rights

EDPD 1995 European Data Protection Directive 1995

ELSI Ethical Legal and Social Implications

GDPR 2016 General Data Protection Regulation 2016

GWAS Genome Wide Association Study

HRA 1998 Human Rights Act 1998

ICO Information Commissioner's Office

IF International Federation

IOC International Olympic Committee

IRB Independent Review Board (see also REC)

IRTP International Registered Testing Pool

ISPPPI International Standard for the Protection of Privacy and Personal Information

ISTI International Standard for Testing and Investigation

MEO Major Event Organisation

NADO National Anti-Doping Organization

NGB National Governing Body

PIE Public Engagement and Involvement

PPP Public Private Partnership

REC Research Ethics Committee (see also IRB)

RTP Registered Testing Pool

TRE Trusted Research Environment

UDHR UN Universal Declaration of Human Rights

UKAD UK Anti-Doping

UNESCO United Nations Educational Scientific and Cultural Organisation

USADA US Anti-Doping Agency

WADA World Anti-Doping Agency

WADC World Anti-Doping Code (latest version, 2021)

WHO World Health Organisation

1 Introduction

This thesis aims to critically evaluate the ethical and governance needs and whether they might usefully be harmonized for global population biobanking, focused on the potential research uses of the World Anti-Doping Agency (WADA) Athlete Data Administration System (ADAMS) biobank data. To do this, a limited overview of European governing instruments relevant to biobanking is presented, with reference to global instruments, to locate biobanking within the regulatory landscape. Secondly, a discussion of harmonization of ethics and governance as it relates to existing and proposed biobank research. Thirdly, a critical examination of the idea of consent to research is set out in detail, as it is widely regarded as the most important concept relating to the ethical governance of biobank research. Fourthly, the thesis presents an overview of anti-doping and situates the development of the movement in its socio-historical contexts, and ADAMS within anti-doping, in order, fifthly, to ethically interrogate the WADA- ADAMS resource and the range of ethical and governance challenges raised by its potential research uses.

ADAMS sits at the intersection of both biobanking and anti-doping in sport, holding health-related and other sensitive data that were not originally collected for research, but for doping control, and therefore requires special ethical attention. To my knowledge this is the first study of the ethics and governance of research using anti-doping data. The ADAMS database is used to apply and test concepts in a real-world setting. The thesis, therefore, performs two functions: to interrogate and contribute to the literature on harmonization of ethics and governance, and consent, *and* to develop recommendations that can inform decision-making regarding the management and potential research uses of ADAMS data. An important component of ethical governance for multi-site research is public and stakeholder involvement and Chapter 7 considers what methods may be more justifiable in the athlete setting and how engagement and involvement can contribute to ethical research. In conclusion, recommendations for WADA policy development and athlete stakeholder engagement, as well as for further research are set out/articulated/presented.

Biobanking is a generic term that refers to processes for the collection, storage and usage of samples and data for biomedical research. The term biobank was first used in the scientific

literature in 1996, in reference to 'human population-based biobanks' but the definition has expanded since (Watson & Hewitt, 2013) to cover the models discussed below. Biobanks have developed since the 1990s as a valuable resource for researchers, giving access to a large number of individuals, and offering opportunities to interrogate a range of health-related artefacts for example, biomarkers for disease susceptibility, and environmental factors in disease. The Expert Group of the European Commission defines biobanks as various types of "biological samples themselves, plus the related databases" (http://ec.europa.eu). The Organisation for Economic Co-operation and Development (OECD) describes biobanks as 'structured resources that can be used for genomic research and which include human biological materials and/or information generated from the analysis of the same; and extensive associated information' (http://www.oecd.org). Biobanks usually include long-term sample and data storage, and might be run by departments, organisations or academic institutions – disease biobanks tend to be the responsibility of hospitals whereas other more general population health biobanks may be run by an organisation independent of the healthcare system. This thesis will focus on data from the healthy; those not identified as patients for the purposes of participation in research.

There are five main models for biobanks: small scale/university, governmental/institutional, population, commercial and virtual (Phillips et al, 2020). Each describes a range of research activities and uses of human-derived samples and data. Biobanks are used in biomedical research, utilising a range of bio-samples including saliva, blood, epithelial and semen to derive data in order to gain new knowledge about a condition, population or health challenge. Latterly, the linkage of datasets within and between biobanks has been undertaken to illuminate the relationships between genomic, environmental and life-style factors in shaping population health (OECD). This thesis focuses on population biobanking, primarily governmental/institutional biobanks, of which WADA-ADAMS is one. ADAMS is an unusual biobank in that the samples and data that comprise its content have been collected for non-medical purposes: doping control. The ethical challenges raised by the particular characteristics of ADAMS are explored in Chapter 6. These kinds of biobanks often operate as consortia and include public-private partnerships. The rationale for this operational model is the broadening and acceleration of research beyond what would be possible for a solely public funded project. A range of operating models and partnerships exist in biobanking and whilst an analysis of those is not the focus of the thesis, the kinds of organisations that have

access to samples and data and the ways in which biobanks operate are relevant to public perception and to governance.

The concept and operationalisation of biobanks has generated concerns around governance, privacy and biomedical research ethics. These are additionally complicated when data or biological samples' governance is distributed across cultures and nation states. This concern about governance and the ways in which complexity increases when working across borders is important because collaboration between repositories and infrastructures is central to effective and responsible biobank research. Increasingly, biobanking takes place across borders, facilitating access and upscaling of samples and data which are needed to enable and enhance biobank-facilitated research for several reasons. A primary reason for this scaling up is the need for large population studies. This may be due to the rarity of a condition or feature requiring combined cohorts; or a range of research uses that require diversity of population. Scale and heterogeneity are means to support the acceleration of research. In addition to operational reasons for collaboration, the shared endeavour of discovery and the sharing of findings and potential benefits from those endeavours may serve to increase a sense of commonality and mutual gain that goes beyond the instrumental, measurable progress of research.

The ongoing development of population-scale biomedical research, incorporating biobanking relies on the development of appropriate ethical oversight and governance and therefore examination of the key concepts on which they rest. It is important to articulate these relationships in a nuanced manner in order to enhance our understanding of contemporary approaches to large scale, multi-location, biomedical research ethics. For the field in general and for ADAMS specifically, biobanking is a social activity and asset- production of common goods from publicly funded research (Christensen in Solbakk, Holm & Hofman 2009: 103). By placing biobank research in a wider societal context and recognizing how it is both created by and creates that context (large scale biomedical research) we can see it as an artefact of an ongoing shift from individual to large scale research and from tissues to data.

Biobanking sits at the intersection of multiple research disciplines and practices, and involves heterogeneous types of actors, including legislators, policy makers, research participants, researchers and funders. It raises issues of private and public interests, protection of individuals, and the development of research that aim to have population-wide benefits. This complexity means that nuanced ethical and regulatory work is needed to provide quality

governance and an ethically responsible environment for the conduct of genetic biobanking activities. The growth of biobanks in terms of volume and connection, network capacity expands not only the range of research uses at a given point in time, but the geographical range and the duration of collections (Harris et al, 2012). The addition of genomic material that can be reproduced and therefore is almost limitless in duration adds further complexity. The linkage of data both sample-derived and from other sources, for example electronic health records, creates a vast and complex network of information, samples and data. Further, distinction is made between materials obtained or created for research and those collected for clinical or other purposes and then used in research. Broadly, these are referred to as primary and secondary uses and the meaning of this rich mass of potential information is as vital as collecting and managing them in the first place. Meaning refers to the contexts and purposes for which the samples and data have been collected, as well as that which follows from analysis and interpretation.

The ethical and governance challenges for global biobank research, and its attempts at harmonization are the core of the thesis. Therefore, in Chapter 6 we will critically examine the WADA-ADAMS resource with the aim of deeper understanding the values and norms that underpin existing processes. Secondly, we identify and challenge and point to ethically justifiable ways to utilise data from ADAMS. The ADAMS biobank was selected because it is a uniquely positioned resource which, despite requests from anti-doping researchers, has not yet been made available for research uses outside of WADA, presenting an opportunity to assess the necessary conditions for ethically justifiable research uses of WADA data may be and how to develop those conditions through engagement and policy.

The ADAMS database is a special case due to the kinds of data held, the purpose and the circumstances in which those data are acquired. The ethical and governance challenges that ADAMS represents will be informed by broader sporting contexts and investigating them will offer insights that are more broadly relevant to social spheres beyond medicine. ADAMS data are heterogeneous by type and population including haematological and steroidal data from the Athlete biological Passport (ABP) and longitudinal due to the requirement to retain data for retrospective testing (ISTI). In addition to novel information that can be gained by interrogating new data, there is potential for further information to be gleaned from existing data. Advances in biotechnology, and the methods by which it may be possible to interrogate and link data sets mean that revisiting existing data can potentially give rise to entirely new information. Patterns of athlete variables such as location/biological/hormonal correlations

raise the potential for new risks to athlete contributors to the biobank, and also to anti-doping programmes. It is ethically relevant that we consider risk of harms in terms of how contributors to ADAMS and the general athlete population might be affected by any harms. Considering how to prevent, reduce or manage risk is integral to ethical research conduct even though in many contexts we accept zero risk may be impossible and the research remains justifiable. Acceptance of minimised risk should be accompanied by procedures and funding to mitigate those harms, should they occur.

The examination of the WADA's ADAMS database and potential secondary uses of the data originally taken for doping control and anti-doping research within WADA highlights the constraining circumstances surrounding current processes for athlete consent to sample taking. Constraints include the potentially coercive circumstances surrounding testing (data and sample collection) and the potential for conflation of consent to testing with consent to data processing for research. The thesis considers how these features may impact the validity of the consent underpinning the testing process, with implications for future actions that are based on that consent. Athletes subject to anti-doping regulation do not have entirely voluntary choice regarding sample and information provision due to the fact that doping controls are mandatory for competitive athletes (a policy that is possible – with states parties' approval – to be applied to recreational athletes as well). It is important, therefore, to understand the nuanced nature and limitations of the consent process in contrast to traditional clinical settings, prior to evaluating the potential secondary uses of athlete doping control data. A further consideration is made of the differing ethical implications between secondary uses of that data for anti-doping research that directly benefits athletes, and for biomedical research uses more generally. A key distinction here is the source of the legitimacy for the action: for anti-doping research this arises from the legitimacy of the wider anti-doping movement, but such a direct base is not clear for broader biomedical uses. To be clear, the question is about the source of legitimacy and not whether the anti-doping movement is legitimate. We base the assumption of legitimacy for anti-doping on the global ratification of the International Convention against Doping in Sport (UNESCO, 2005).

The history and development of global anti-doping practises and governance are explored in Chapter 2, to situate the ethical challenges of research uses of athlete data within the sporting and research worlds more generally and understand how they inform those ethical challenges thrown up by the potential secondary uses of ADAMS. The anti-doping movement, led by

WADA in conjunction with other Anti-Doping Organisations (ADOs) such as national and international sport federations, and the International Olympic Committee (IOC), has been criticised *inter alia* as being problematic in terms of consent processes, representation for athletes and fairness. This is relevant to the development of ethical processes for collection, storage and research access for sample-derived and other athlete data, specifically those contained in the WADA's ADAMS biobank. Work undertaken here to inform ethical practice for ADAMS will have application in the wider field of biobanking and population research as there are a number of shared ethical and governance issues.

The range of ethical and governance issues associated with biobanking can be divided into: first, traditional research ethics concerns; second, social and organizational concerns; and third, technical and methodological concerns (Lipworth et al, 2017). This thesis is primarily concerned with traditional ethical concerns and, secondarily, with social and organisational concerns. These include ethically justifiable ways to collect, store and make use of materials and data across a range of contexts and over long periods.

It is important to state at the outset, that there is no universally agreed definition of the term "biobank". It is, however, widely understood to mean a collection of biological samples and accompanying data that have been taken for the purpose of research. Latterly, the term biobank has been used to describe infrastructure beyond simply collecting and storing data and samples. BBMRI and biobanks are large scale resources that link biological with health or other biographical data. They are often set up for prospective studies but can also use existing sample collections and are sometimes mixed. Biobanks differ from *biorepositories*, since the latter serve merely as a store for biological samples taken in the run of clinical investigations. Biorepositories store, for example, excess biopsy tissues and blood from testing. Such resources may later be used for research, but they are not usually collected solely for that purpose. Biobank research projects range from disease-specific, for example, the Breast Cancer Now Tissue Bank (breastcancernow.org), to population scale, for example, UKBiobank (ukbiobank.ac.uk). This heterogeneity raises many challenges for ethics and governance since a one-size-fits-all approach to biobanks may be insensitive to the specific needs of particular biobanks and their participants.

It is a feature of large-scale biobanks re-using data that the sources of the data stored within them will arise from research projects or clinical investigations that themselves have been produced under differing conditions. A significant advantage of the modern biobank over

smaller scale research is the possibility of combining of collections to form huge data sets that can be linked with other types of data to investigate a wide range of questions. There are numerous potential scientific and social benefits from such research, from how our genetic makeup interacts with environment, to drug targeting to social determinants of health, to anti-doping or even sports performance enhancement. The use of biobanks to store tissue or genetic material is not new, but the internationalization, scale and combination of genotypic with phenotypic data is a more recent development. The ability to discover genomic information about a person by examining their phenotypic and associated health information presents potential risks that were either non-existent or significantly less likely at the start of the emergence of biobanking. These aspects have generated new normative challenges to researchers and clinicians and new challenges will continue to arise with both the increase in scale and technological ability to interrogate data in ways yet unknown. Biobank research has rapidly grown in, both scale and areas of application. Appropriately governed, it offers potential benefits that are possible to foresee such advances as personalised treatment, and disease risk prediction, among other things. Ensuring the integrity of such research whilst protecting participant interests is fundamental if researchers are to ethically explore and exploit all the possibilities of biobanking. The complexity and 'unknown' elements of these approaches require deep consideration of underlying norms and the development of appropriate governance that reflects the issues raised. Consent is a central element of research ethics in the biobanking context. Current models may be challenged by the informational uncertainty of potential research applications of biobank resources.

Understanding whether and how different consent models can be justified in population scale biobank research -as opposed to more traditional settings - and what contribution consent makes to the overall ethical governance of the research present important ethical challenges. The literature around consent is extensive and multidisciplinary (See Allen & McNamara, 2011; Caulfield & Murdoch, 2017; Eriksson & Helgesson, 2005; Kaye et al, 2015; Manson & O'Neill, 2007; Ploug & Holm, 2016; Steinsbekk et al, 2013; Sheehan et al, 2019; Tindana et al, 2019). A range of models of consent, i.e., ways of operationalising the concept, exist. Those more frequently employed are considered here and comprise (i) specific informed, ii) dynamic, iii) broad, iv) blanket, iv) tiered and v) meta-consent. They will be critically examined for their appropriateness in population biobanking. Trust and trustworthiness are also important components of research ethics and population scale research. In particular, research reliant upon secondary uses of data or samples raises specific challenges to the

development of trust and the demonstration of trustworthiness. The scale and remote nature of data work is also a challenge to the norms on which clinical ethics, and therefore human research ethics, are based. There may be little - and sometimes no - opportunity for direct interaction between data contributor and researcher, nor for the reporting of information at an individual level. Where data are fully anonymised, there is no practical right to withdraw since identification of the participant who wishes to withdraw is rendered impossible by the anonymisation procedures. Even where data are identifiable and therefore contact is theoretically possible there may be good reasons not to seek further consent. The right to withdraw and its relationship with consent is discussed further in Chapter 4 and Chapter 6. Beyond trust and consent, there are acknowledged differences in ethics, governance and regulation for population research and uses of data more generally between legal jurisdictions and in attitudes to such between cultures. For example, differing conceptions of autonomy and privacy underpinned by conceptions of the individual and communal.

The regulation and governance of multinational biobanking is often described as being fragmented (e.g., Harmon and Laurie, 2011; Laurie, 2017; Gottweis & Zatloukal, 2007). Global efforts are being made to address this by attempting to harmonize regulatory and governance frameworks that complement legislation or provide a 'soft law' solution where either no legislation exists or would not be the most effective approach (GA4GH, 2021). Research governance and regulation across geographic and jurisdictional boundaries requires a flexibility that allows for interpretation in local context whilst promoting shared norms that ought to be upheld. No single set of universal principles or legal-regulatory instrument(s) are likely to be able to provide that. Moving towards harmonization of existing governance, in combination with the development of new frameworks or instruments as needed, is a somewhat open-ended stance that may provide the means necessary to enable global research cooperation to facilitate research progress (Tasse, 2013).

For governance to be ethically and operationally robust, trust and trustworthiness are usually required with the exception being in systems that are not based on trust, but reliant on transparency and reliability. Trust can be described as an attitude of the individuals and groups participating in research and trustworthiness as a characteristic or condition of organisations (Jongsma & Bredenoord, 2018). These terms are often used interchangeably but are not synonyms and are here considered as complementary aspects of research interactions. Trust requires confidence in the competence of another, and in their good will not to harm the person who is vulnerable to abuse at the hand of that competence and will

(Baier, 1986). Much concern has been levelled at WADA because of their lack of stakeholder engagement and their hierarchical and sometimes non-transparent processes. This speaks to the vulnerability of athletes within the systems and challenges WADA's reputation as trustworthy. As WADA is a global organisation, governing the actions and systems of the global anti-doping movement via Code signatory sporting bodies, ways and means for the consistent and fair application of the Code and accompanying standards must be found. This is true for research as well as for other core activities.

One ethical claim made by WADA is that harmonized rules make for good, authentic, sport. In effect, they establish international standards. These exist for testing and investigations (ISTI), laboratories (ISL), therapeutic use exemptions (ISTUE), the Prohibited List (the List), the protection of privacy and personal information (ISPPPI), Code compliance (ISCCS), results management (ISRM) and the standard for education (ISE) which was introduced in 2021. Doping Control being standardised and compliance to the Code and accompanying standards monitored with sanctions for transgression, this existing framework raises the question of how WADA might form an International Standard for secondary use of data for research purposes a) for anti-doping and b) for biomedical research. The question of how to approach creating conditions for research uses of ADAM, including the potential for developing standards and for the harmonization of ethical governance is addressed in Chapter 3 and Chapter 6.

A harmonization approach that is based on a pluralistic framework may facilitate movement towards a common goal while remaining sensitive to legal and contextual differences. This supports commonly understood ethical governance in diverse settings and has value both intrinsically and in legitimising international governance. Establishing structures capable of encompassing diverse perspectives without recourse either to laissez-faire or relativism on the one hand, and rigid uniformity on the other, is the model most likely to achieve consensus and legitimacy. Creating conditions for ethically justifiable research that serves the public interest by being sensitive to the potential differences in the conception of interests, within agreed bounds, is a central goal of harmonizing governance for research. Harmonization, a concept taken from international legal discourse, is an approach to managing multi-party governance that aims to facilitate compliance with agreed rules or frameworks whilst allowing for plural approaches to implementation. It should be noted that there is no claim to apply harmonization in a strict legal sense, nor does this thesis attempt formal legal analysis.

Whilst there is some formal harmonization of legal instruments referred to in discussion of existing consortia and for WADA's anti-doping activities, it is not the sense in which we might hope to see it for the potential future research activity with which this thesis is concerned.

In addition to governance, consent and harmonization, key questions concerning global biobanking refer to whom the relevant 'publics' might be (for engagement and benefit sharing purposes), particularly in population biobank collection and research, conducted on the basis of public interest. In the anti-doping context, the primary relevant population is elite athletes with data in ADAMS, expanding to the general athlete population subject to doping control.

Population biobanking that collects and uses contributions from 'healthy populations', rather than those working with condition or patient populations is the main biobank type in focus, though it could be argued that athlete populations are closer to patient populations than the general public in terms of special interests due to their potential to benefit from research outcomes that contribute to anti-doping efforts. This may also be true for other sports-related research but less so for broader biomedical (secondary) uses of the ADAMS data. Using ADAMS data for research into anti-doping may seem relatively straight forward as the primary interest group is those who are already subject to and invested in anti-doping activity i.e., athletes. The use of public health as a central justification for WADA-led doping controls raises important ethical questions and these will also be explored in the thesis. As well as the public health and consent, data management issues, athlete involvement and representation in decisions about secondary uses of ADAMS is a challenge. This relates to wider concerns about athlete voice in anti-doping and to interest groups being meaningfully involved in other contexts within biomedical research.

In concluding, it is argued that WADAs ADAMS biobanks are an ethically justifiable means to further anti-doping and potentially broader biomedical research, provided that some key features are in place. This is based on interrogating and then applying key concepts in harmonization and governance in ethically justifiable, achievable ways. Finally, recommendations are made for adapting current systems and processes including consent and athlete education, as well as further work on determining what governance models may be acceptable to athletes concerning research uses of their data.

2 Regulation

Biobanks and research tissue bank repositories are not new but have substantially increased in scope, scale and number. Over the last decade, their diversity of purpose has also expanded. However, accompanying this growth is a number of high-profile scandals which have highlighted the need for more and better regulation and ethical oversight of research conducted on human samples and associated data (Liddle and Hall, 2005). The regulatory landscape surrounding bio-banking and research using genetic data is widely described as complex and fragmented (Laurie 2011). The complexity and piecemeal nature of governance regarding these types of research has led to a large body of literature from legal, bioethics and research scholars as well as government and other bodies.

Tissue and data are regulated separately but increasingly co-exist in biobank research:

> 'A Health Database is a system for collecting, organizing and storing health information. A Biobank is a collection of biological material and associated data. Biological material refers to a sample obtained from an individual human being, living or deceased, which can provide biological information, including genetic information, about that individual. Health Databases and Biobanks are both collections on individuals and population, and both give rise to the similar concerns about dignity, autonomy, privacy, confidentiality and discrimination' from WMA Declaration of Taipei 2016 (Preamble, point 4).

Governance is made up of legislation, policy, guidelines and professional codes that have developed separately, and usually include rather than specify biobanking. This makes understanding precisely the ethical and legal requirements for conducting biobank research difficult. This chapter refers to regulation in a broad sense, including but not limited to the strict legal definition whereby regulation has the effect of a law and is considered as a

restriction that is imposed by authorities, to make people follow the desired code of conduct. Soft law, governance frameworks and codes of conduct are included as well as policies, made by individuals, organizations, and also governments. Some of the ongoing challenges at sector level relating to governance and regulation for the biobanking include transparency and harmonization. Harmonization is not well defined and the specific challenges involved will be covered in greater detail in the following chapter. This chapter is not an attempt at formal legal analysis, but will introduce the key pieces of legislation relevant to biobank research and in particular to collaborative working including data sharing, and the lack of coherence between the relevant instruments. Given that biobanking is by nature interdisciplinary and that global research collaboration interacts with and is governed by an extraordinary number of guidelines, codes, laws and other instruments, this chapter is a limited overview of the key concepts, instruments, and types of instruments, that relate to biobanking and health research governance, with the aim of situating biobanking within its regulatory and societal context. We begin with international governance and regulation and then move to the EU and UK, followed by a consideration of the challenges to international collaborative research that arise from the regulatory landscape and the role of key human rights legislation. Finally, there is a discussion of the limitations of the legal and regulatory approaches to biobank governance as it currently exists. Key instruments are listed chronologically in Figure.1.

Figure.1

Key Regulatory Instruments applicable to biobank research. Adapted from the Ethical and Legal Codes and Policies Guiding Data Sharing Behaviour (GA4GH).

• Constitution of the World Health Organization (WHO 1946)
• Bermuda Principles on Human Genome Sequencing (1996)
• Universal Declaration on the Human Genome and Human Rights (UNESCO 1997)
• Convention on Human Rights and Biomedicine (Council of Europe 1997)
• Statement on DNA Sampling: Control and Access (HUGO 1998)
• Statement on Human Genomic Databases (HUGO Ethics Committee 2002)
• Declaration of Ethical Considerations regarding Health Databases (WMA 2002)
• International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS,
WHO 2002)
• Budapest Open Access Initiative (2002)
• Sharing Data from Large-scale Biological Research Projects: A System of Tripartite Responsibility (Fort Lauderdale Statement, 2003)
• International Declaration on Human Genetic Data (UNESCO, IBC 2003)
• European Society of Human Genetics: Data Storage and DNA Banking for Biomedical Research
(ESHG 2003)
• Universal Declaration on Bioethics and Human Rights (UNESCO 2005)
• Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Biomedical Research (Council of Europe 2005)
• Recommendation Rec (2006) 4 of the Committee of Ministers to Member States on Research on
Biological Materials of Human Origin (Council of Europe 2006)
• OECD Principles and Guidelines for Access to Research Data from Public Funding (OECD
2007)
• International Ethical Guidelines for Epidemiological Studies (CIOMS, WHO 2008)
• Recommendations from the 2008 International Summit on Proteomics Data Release and Sharing

Policy (Amsterdam Principles, 2008)

• Guidelines for Human Biobanks and Genetic Research Databases (OECD 2008, 2009)

• 2012 Best Practices for Repositories: Collection, Storage, Retrieval and Distribution of Biological Material for Research (ISBER 2012)

• Responsible Conduct in the Global Research Enterprise: A Policy Report (InterAcademy Council
2012)

• Guidelines governing the Protection of Privacy and Transborder Flows of Personal Data (OECD
2013)

Declaration of Taipei (WMA 2016)

Transparency is a particular challenge for biobank governance due to the complexity of the regulatory and governance landscape and the sheer number of relevant but often non-binding, instruments. Key instruments are shown in Figure 1. There currently exists no single overarching instrument that specifically governs international bio-banking and genetic data research and it is a field that continues to develop at speed. In addition to the geographical and jurisdictional, governance complexity, the inductive nature of the research based on, for example, linking data derived from bio-samples with health and other types of data creates a number of problems for existing procedures and the ways in which both the public as participants and receptors, and the 'traditional' research establishment conceive of large-scale international biobank research. What counts as health data is not clearly defined whereas the Human Tissue Act 2004, GDPR 2016, DPA 2018 and other instruments are clear on what is to be considered human biological material and the restrictions on the ways in which it can be used. Soft law, policy, guidelines, professional codes, Articles of the Universal Declaration on Human Rights and other legislative instruments that do not specifically refer to biobank research are used to govern 'piecemeal'.

2.1 WMA Declarations

'The World Medical Association's (WMA) Declaration of Helsinki guidelines for medical research on human beings aim to 'promote the ethical conduct of research and to protect human subjects from associated risks' (WMA, 2013). The Declaration of Helsinki was the first set of international research guidelines that required research participants to provide informed consent and the first iteration was produced in 1964 as a policy response to support the Nuremberg Code as part of the postwar development of protections for research participants (subjects in the language of the earlier editions).

The 2013 version of the Declaration of Helskini is the current edition and as with all previous iterations there is not explicit provision for biobanking. To remedy this in light of the expansion of the field, the WMA Declaration of Taipei was adopted by the 53rd WMA General Assembly, 2002 and revised by the 67th WMA General Assembly in 2016. The declaration 'lays down ethical principles for medical research involving human subjects, including the importance of protecting the dignity, autonomy, privacy and confidentiality of research subjects, and obtaining informed consent for using identifiable human biological

material and data' (WMA It is written to be applied in concordance with the Declaration of Helsinki principles and does not replace them but adds provision for biobank and health database research and related activities. It should be noted that in recognition of the ever-increasing range of settings in which biological materials and health data might be created, analysed and stored, 'this policy aims to address any use of health databases and biobanks excluding individual treatment and is not restricted to research'. Neither WMA declaration is legally binding, but both have been influential in the development and implementation of national legislation and professional codes of practice.

The Declaration of Taipei (2016) sets out ethical principles and governance requirements for the activities of biobanks and health databases, including the bases for valid consent and privacy protections. It requires that 'reasonable efforts' be made to seek out persons for whom data but not consent is held but does not specify what 'reasonable efforts' might look like, as the capacity and resources available to institutions will vary greatly from country to country and across the public and private sectors. Taipei requires independent ethical oversight of health databases and biobanks to include checks on consent and ongoing monitoring of activity.

Governance must be based on protection of individuals, transparency, participation and inclusion and accountability. Section 21 of the preamble sets out elements to be included in good governance for example 'Arrangements for protecting dignity, autonomy, privacy and preventing discrimination' but does not define terms nor give specific instruction on how these might be achieved. The declarations are conceived as guidance for the formulation of policies and legislation by 'relevant authorities' and in the case of statutes this will be national or regional governments.

> 'Physicians must consider the ethical, legal and regulatory norms and standards for Health Database and Biobanks in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for individuals and population set forth in this Declaration'

(WMA Declaration of Taipei Preamble 2016 section 6) is clear that ethical and legal requirements should not provide lesser protections than those set out in the principles, but with no way to enforce this it can only be advisory. The consideration of ethical, legal and

regulatory norms in their own countries as well as those that are applicable internationally[1] speaks to a pluralistic governance that would seem to be a logical approach, however the statement lacks clarity. There is no specific guidance regarding how differences between national and international standards and ethics should be reconciled to promote research while protecting participants and producing public benefit.

2.2 GDPR and DPA (2018)

This section will outline the GDPR and DPA 2018 and the types of data relevant to health research and biobanking with those statutory and other associated instruments are concerned. Personal data is defined by the ICO as information that relates to an individual. 'That individual must be identified or identifiable either directly or indirectly from one or more identifiers or from factors specific to the individual' (ICO, 2021). but it is unclear as to whether genetic data are or should be always considered to be personal data. Under the GDPR, anonymized data are not personal and therefore do not require the same protections as identifiable data. However, it can be argued that genetic data remain potentially identifiable even where 'anonymised'. Not only is there a risk of identifying the person from which the data originate, but persons to whom they are genetically related. In addition to direct identification risks from genetic data, the linkage of data derived from samples and associated health and other types of data can build a rich picture that may potentially risk identification not only of blood relatives, but others to whom the data originator is connected for example sports team-mates, non-genetic family members and partners.

Data that are identifiable, or anonymized in line with the ICO Anonymisation Code of Practice but linked with or processed in a way that it could be linked with an identifiable person, is considered personal data for the purposes of governance and regulation. In the UK the GDPR and related UK Data Protection Act (DPA) 2018 was designed to update the DPA 1998 and meet the standards of the GDPR with some UK-specific features. The DPA 2018 was developed ahead of the UK's exit from the EU to ensure that collaborative research and the sharing of data between the UK and EU can still take place. The GDPR describes 'special category data' which require both a lawful basis for processing (Art.6), and a condition for processing (Art.9 (2)) due to the more sensitive nature of these types of data. Genetic data is listed as one of the special category data types as are health data more generally. This is justified on the grounds that 'this type of data could create more significant risks to a

[1] See Table 1 p23-24 for further definitions of data types from the GDPR.

person's fundamental rights and freedoms. For example, by putting them at risk of unlawful discrimination' (ICO, 2019: 47).

The DPA 2018 refers to processing of data for 'archiving, research and statistical purposes' subject to 'appropriate safeguards for the rights and freedoms of the data subject' and makes explicit that processing for research will not met the GDPR standards (Art 89 (1)) if 'it is likely to cause substantial damage or substantial distress to a data subject'. This provision does not clearly define substantial or distress and while case law exists for older legislation, as yet the GDPR/DPA 2018 have not been tested on these points. Additionally, the legal definition of substantial distress may not correlate with participant or family experiences or perceptions. This is due to distress being a subjective experience whereby perceptions of risk and harms arising from data processing arise on a spectrum not only across populations, but also over time and according to data type (See Table 1.1) and proposed uses[2].

[2] See p85-86 on harming and wronging including distress

2.3 Data types: Definitions from the GDPR.

Table 1. Data Types in the GDPR

Data Type	GDPR definition	Comments
Personal data: any information relating to an identified or identifiable natural person (data subject) (Article 4[1] of the GDPR).	In practical terms, the definition covers all types of data and information, which have some connection to a specific, identifiable person. The connection can exist (1) on the basis of the content of the data or information itself—for example, in the case of biometric identifiers—or (2) on the basis of the possibility of combining data with other data sets, which would allow a connection to be made to a specific individual.	

Pseudonymous data: data that have been produced via pseudonymization (Article 4(5) of the GDPR).	The latter means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject, without the use of additional information, provided that such additional information is kept separate. Practically, pseudonymization involves coding of data. Pseudonymous data are still considered personal (Recital 26).	
Anonymous data: data from which no connection to a specific identifiable person can be drawn, based on either the specific data alone or through linking to other datasets.	Anonymous data fall outside applicability of the GDPR (Recital 26).	

The GDPR developed out of a recognition that existing European and Member State regulation was insufficient to protect persons in the face of evolving data techniques and uses (Dove, 2018; Shabani, 2021). Additionally that there was inequality of protection between different nations and no explicit provision for the protection of data from European citizens once outside of EU territory. I will not attempt a full 'natural history' of the GDPR here, but Dove (2018) draws out the development, influences and implications of the GDPR in the global landscape of biomedical research regulation. The 'one way compliance' of the GDPR,

in that third countries must comply to the EU's approach without expectation of reciprocity. 'if there is to be international harmonization around sharing genomic data, then an international set of rules has to be found between jurisdictions' (Townend, 2018:658). This statement is in reference to legal instruments but does not limit the potential for 'solutions' for international harmonization to Law. Whilst the primary focus in discussion of harmonization for research and data sharing is on inter-jurisdictional and territorial settings, there is still complexity and uncertainty around sharing data within a jurisdiction or geographic territory. Sharing between a research biobank, healthcare provider, academic and other institutions is far from straightforward within contexts as well as between them.

The 'research exemption' as it is commonly known, is justified on the basis of 'public interests' a term that itself is not well defined and is certainly not static[3]. What counts as public goods and interests shifts over time and may be understood differently for example by different socio-economic groups and relationship to research. The benefits of genomic and other biobank research are disproportionately seen in more affluent societies, but also by higher socio-economic groups within those societies. The data is also overwhelmingly white European/Caucasian in origin and much has been written about the potential problems this causes for ethical and effective population research, not to mention the basic inequality and injustice of excluding made-vulnerable groups either from participation or from accessing benefit of the research following their participation. To put it briefly 'the benefits must contribute to levelling social and natural differences' (Christensen 2009:110) There is much more to discuss regarding the potential for post-hoc 'exploitation' but it is outside the scope of this work, which is chiefly concerned with ethically justifiable uses of biobank data and the practices that support research for biomedical and health purposes. The actual and potential limits of responsibility for biobanks regarding data that is used by third parties, including any downstream effects, is discussed in Chapter 6 with specific reference to the WADA-ADAMS database.

The GDPR and DPA also cover the transfer of data to 'third countries' or organisations outside of the EU requiring that standards of protection for personal data are sufficiently adequate. This is because such sharing of data may take place with the subject's consent, where necessary for a contract, or for reasons of public interest. The data minimization principle applies across all areas of the GDPR and 'must limit personal data collection,

[3] See p38 for an overview of public interest

storage, and usage to data that is relevant, adequate, and absolutely necessary for carrying out the purpose for which the data is processed' (ICO, 2019). GDPR Article 20 - the right of the data subject to have access to data in a structured and readable format and to be able to transmit those data to another controller as they see fit. As Chassang et al (2018) point out this raises questions for biobanking activities given the complexity and number of interested parties.

European Data Protection Board (EDPB) guidelines cover data portability in the context of health research. Data portability is different to the right to access personal data as per Article 15 GDPR. Data portability was introduced to enhance rights but also to support data economy and aid the multiple uses of data (ICO, 2018:297) Processes for scientific research, including acquisition, sorting and destruction of data as well as quality assurance. For research purposes this means only obtaining and linking relevant data and sharing it as needed to conduct the research. How relevancy is determined is a pertinent question in the context of biobanking and large scale biomedical data research. This is because where massive data sets are linked and interrogated for patterns, health as a well as other data types e.g. administrative or routine data are linked with data derived from samples, relevancy may only become apparent after processing. The research exemption allows for this leeway legally, but there may be some grey areas in ethical terms. Not least of which will be the level of understanding it is possible for members of the public to have regarding highly complex and rapidly evolving technical research approaches.

> 'While responsive regulation is designed to make effective state regulatory law practicably enforceable by allowing most regulation to be transacted cheaply at the base of the pyramid, nevertheless many states, especially poor ones, lack the resources to escalate to more expensive measures' (Braithwaite 2011:507).

The influence of globalisation on research and research norms/norms of science- ideas globalise following similar patterns of postcolonial dominance as the power structures and (funding and access to resources and to the products and therefore benefits) of science (Article 27 UNDHR) and to the underlying notion of progressing science that informs and is made explicit in the GDPR and related regulation. Without results or research findings there can be no benefits for the public, but that is not reason for researchers to be given carte-blanche. Good governance and person respecting methods are essential, however being so cautious that no research is possible is also unethical. A balance must be struck.

Research participation places a burden on participants, albeit less so in data based research than in more invasive approaches. Taking someone's data or samples and then not using them for the purpose intended is wasteful of potential benefit and of the participant or contributor's efforts; all the more so as they are often not recompensed. The non-use problem in biobanking is significant due to the burden placed on contributors and participants, the resources involved in the collection, storage and management of the artefacts and the loss of potential knowledge and downstream applications leading to societal benefit. While all research benefit is potential until realised, meaning that that there is no guarantee of results or tangible benefit to be made to those contributing bio materials and data; the narrative around asking for participation is of contributing to societal good. Therefore, if materials, data go unused it is a contradiction of the premise upon which they were given. We might even go so far as to say that, without being spelled out during the decisional (and consent, where appropriate) process, failure to make the most ethically justifiable use from contributed materials including data could be a challenge to participant autonomy, certainly to the informedness aspect of their consent. This non-use problem is not captured in current regulation, and may be difficult to enforce through a top down approach, nevertheless it is worthy of considered attention and should be woven into future governance for biobanks, for example in the event of ADAMS allowing access to researchers there would be opportunity to require reporting that accounts for use and communication of that use with justification for not doing. Careful design of governance and regulation will necessarily be accompanied by ethical oversight.

The UKECA (UK Ethics Committee Authority) oversees the activities of local RECs and is currently accountable to the EU. It requires biobanks and research tissue banks to register with the UKCRC (UK Clinical Research Collaboration) tissue bank directory (launched 2016) as a condition of favourable REC decision . The HRA also encourage early registration with the UKCRC, but do not enforce it. There are separate clinical research networks for the four nations of the UK and the NREAP (National Research Ethics Advisors Panel established by the Research Ethics Service under the GAfREC- Government Arrangements for Research Ethics Committees which is aimed at harmonizing REC responsibilities across the UK). This structure is designed for clinical research however it is mentioned here as it may offer some insight into best practice regarding oversight for biomedical research uses of ADAMS data. As with the other existing tools and frameworks, where it may not be appropriate to apply

wholesale, there are opportunities for learning from established biomedical research governance for WADA and other stakeholders.

The Human Tissue Authority licence biobanks in the UK. Where a biobank organization has an HTA licence, it is not necessary for individual researchers to acquire one. A further requirement is the return or destruction of samples at the end of project and that nothing is transferred to any third party without HTA approval. The HTA does not govern data, but is applied in concert with the DPA, GDPR. Research tissue or biobank approval will cover the majority of research carried out using the resource, but increasing collaborative work and data linkage from multiple sources pose challenges. Having set out some of the key international instruments and regulatory tools in the UK and EU, we now turn to the inter. This is important in the context of biobanking as international cooperation is vital for much of the global research community and the complexity and lack of coherence hinders those efforts.

2.4 Rights and Obligations

Rights and obligations may be created by the perception of biobank research as societal good. For example, a potential duty to take part in research that benefits society may exist in tension with the individual right to refuse or withdraw and the central role of consent in all forms of research involving humans. We might ask, is research participation a part of citizenship? The ‘right to benefit from scientific progress’ is strongly linked with the right to participate in cultural life (Porsdamm & Mann 2017) and this can be understood as the right not just to benefit but to take part in and to shape research and its governance. Knoppers (2017) refers to the right to benefit from science as an ‘orphan right’ because it has been overlooked however there has been renewed interest in this right recently.

Human rights are based on a universal conception of the value and entitlement that exists by virtue of being human, which has been critiqued as being Western Imperialist rather than truly universal (Deacon, 2003). This is a complex area of international relations and political philosophy that it is not possible to attempt to fully interrogate here, however universality

sought in research governance may be accused of similar bias. Particularly so in the context of research conducted on and with groups for whom there is no realistic likelihood of benefitting from that research. This may be for a number of reasons, among the most common are lack of resource needed to implement findings, for example to buy quantities of a new drug; lack of trained personnel and/or research capacity in a particular field (Tindana etal, 2019). Increasingly, it is a requirement of research funders that local populations receive benefits from research, in order to avoid 'helicopter research' that has been prevalent in low income settings in the past (Haelewaters et al, 2021). Interestingly, calls for open data that are seen to be a way of democratising and opening up access to research and its products, can have the opposite effect in low resource settings: Data can be described as the 'value' and the use of the data to implement a discovery or change, the measurable 'impact'. Therefore open publishing of such data can diminish power for researchers in low resource settings where maintaining control of data might prove valuable: a resource that can be sold or used to gain resources, credibility and ameliorate other deficits. (Parry, 2020).

A human rights approach to biomedical research may sit in conflict with a communitarian approach. Communitarian in this context refers to an approach that 'propagates the need of societies to take the collective as a primary point of reference – arguably dates back to the earliest days of political philosophy, it is often seen to have emerged as a reaction to John Rawls' Theory of Justice (1971)' (Prainsack & Buyx, 2011: x).

Communitarianism places community and community goods to the fore, 'challenging the hierarchy between dominant values in ethics (particularly with respect to autonomy)… Reciprocity, mutuality, citizenry, universality and solidarity, are used points of reference in communitarianism and the concept of solidarity that is central to communitarians centres around the 'preservation of a particular shared understanding of society and its goals, as well as a shared idea of the good life'(Prainsack & Buyx, 2011: x) i.e., it is based on a common good. Human rights are generally located with the individual rather than the group, although the right to benefit from science locates benefit in community; society and not solely at the level of the individual. It therefore seems possible, at least on paper, that a human rights and a communitarian or societal-benefit model can complement each other. Whether one believes that biobank research is a product of and produces goods that reflect important values in society will greatly influence how one perceives the rights and duties involved. If taking an individual approach then consent becomes paramount. However it seems reasonable not to expect total freedom to choose, but freedom to choose within a set of parameters that further

the goods and values of society. Rights do not sit outside of our roles in society and this is accepted in many areas of life (Sjoberg et al, 2001). A well-used example is the mandated and enforceable wearing of seatbelts in privately owned vehicles. Therefore it might seem common sense to demand to require similar contribution or compliance in research that benefits society, especially where it does not impose a significant burden on individual participants. In this way, we might differentiate data or other forms of 'non-invasive' research from interventionist clinical trials.

The ways in which we perceive the common good, as being something determined by society, or as something that enables people to choose for themselves how to live a good life, affects how we think about the rights and duties involved in biobank research. We must be mindful of the inequalities that affect how people are able, or not, to make free choices about research and the goods in their lives. Not all are equally empowered and not all stand to benefit equally: there is a widely acknowledged lack of genetic and socio-economic/social diversity in biobank cohorts within and between populations globally (UK Biobank, H3Africa). One framework that may usefully be applied to questions of benefit and equitable access is that of human rights, as set out in the Universal Declaration of Human Rights (1948) and supporting instruments.

Article 2 of the *Universal Declaration of Human Rights* states: "Everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind such as race, color, sex, language, religion, political or other opinion, national or social origin, property, birth or other status." Concepts such as 'race', 'sex', 'political' and so on employed in the *Declaration* are based on modernist assumptions of ahistorical and static categories (Steinmetz, 2016). However, those concepts are socially and historically constructed and therefore subject to shifts in meaning and to be imbued with different levels of importance over time. This means that it is likely no one overarching law will be appropriate (Fischer-Lescano, & Teubner, 2004). For some this leads to cultural relativism as the only realistic paradigm (Benedict, 2004). That is not the view taken here, rather we suggest that a pluralistic approach, defined as recognizing that multiple values can exist concurrently and even be contradictory whilst being valid and without necessarily deciding which ones are more important than others, may be viable. Pluralistic research ethics requires the careful consideration of potentially competing values and working out which are most appropriate or relevant for a given case/context/situation. It is not the assumption that all values are of equal value, nor that there exists an infinite number of possible values for humans to hold

(Chomsky & Reynolds, 2016). Values are neither static nor ahistorical. We can see this with shifts in research ethics as 'widening of the moral sphere'. Moral disagreements can be debated whilst retaining one's own position and identity and at the same time allowing another party theirs. The role of pluralism in the attempts at harmonization of the ethics and governance of population biobanking is further explored in Chapter 6.

Development of international norms is needed because of the lack of coherence in existing international and national laws. Norms can provide guidance to researchers where legislation or policy is lacking at national level. To be enforceable they would need to be drawn down into instruments, however an increase in 'top-down' legislating may not be the most effective or ethical way to proceed. The complexity of governing biobanking arises not just from the laws, guidelines, and policies but also from the fact that self-regulation has always had a significant role in research culture. It is not as simple as regulation following scientific developments, although it is easy to see why it might be perceived that way if one were solely to consider the major regulatory instruments. One of the elements that can affect what regulation is applicable and applied to biobanks is how they are categorized: in clinical biobanks for example the therapeutic and research distinction is not always clear. Particularly so in hospital-based tissue repositories where participant-patients may consent to treatments alongside research uses. or in fact may not seek consent as it may be presumed (with an op-out, but one that is often unknown to patients) (Lockhart et al, 2012).

Contribution to biobank research can therefore be conceived of as a means to benefit those who have most to gain and who may not themselves be able to participate. 'Research and other Health Databases and Biobanks related activities should contribute to the benefit of society, in particular public health objectives' (WMA Declaration of Taipei Preamble 2016 s8). Where those who have least to gain are the same persons, it may be claimed that they should not refuse to participate based on a duty as functioning members of a society to assist those in greater need. For example, if I am a healthy person asked to contribute samples that replenish themselves or do not otherwise harm me by being taken in order to conduct research that will potentially alleviate suffering in some way e.g. discover risk factors for a disease. This argument may carry particular weight in the sporting world if one considers the benefits to athletes from improving anti-doping measures through research using their data and samples. This is discussed further in Chapter 6**.**

Ethics and governance frameworks set up and described as protecting interests of participants and public in the 'public interest' and for 'public good. They can also be used to measure performance of a body or bodies against a framework and are a means to hold a biobank or network accountable, providing evaluation to inform the next generation of governance and supporting transparency of processes as a means of demonstrating trustworthiness.
Public good and public interest are notoriously abstract (Taylor & Whitton, 2020) and not easily delineated, often used interchangeably.
Taylor & Whitton propose that

> 'the public interest requires any (unavoidable) trade-off between "common interests" (i.e., those universally held by members of a community) such as the interests in privacy and the benefits of health research, to be justified in terms that those affected have reason to accept and which respect individual objection in almost all circumstances' (2020:3).

They provide this proposal with the aim of 'a practicable but meaningful test capable of discerning whether research processing is "in the public interest"'(that is sufficiently nuanced to respond to context but able to provide a consistent measure against which actions can be evaluated (my own and others' by me). The approach to public interest on which the test is based, lends itself to the incorporation of public deliberations in order to examine what might be considered acceptable with regard to data uses. We can apply this directly to the ADAMS context with athletes as the relevant public (See Chapter 7 for more detail on public involvement and engagement, and who should be included). It also centres the individual in requiring that the public interest 'respect individual objection in almost all circumstances' (2020:3). This aligns with dominant conceptions of consent and autonomy however the relational model, centring the relations between persons and expressed in terms of solidarity and the ethic of care (Held, 2006) challenges the a priori position of autonomy. (See p50-51 for autonomy, solidary and the communitarian turn). According to Held (1978; 2006) he assumption that the number of people determines something as 'public' is mistaken- there is no way to demonstrate that the majority is ethically equivalent to the public; and 'empirically, majoritarian decisions rest upon mere superior force'. Therefore, in determining what counts as 'in the public interest' for research uses of biobank data ongoing careful work is needed to examine the shared values and potential benefit for the public of a proposed research endeavour. Weight of numbers is not irrelevant but it is not sufficient, to establish whether something is in, or promotes, the public good (Held, 1978, 2006).

Conceptualising public interest and the 'relevant goods' matters for potential research applications of ADAMS data, and broader population biobanking because of the reliance on the public interest as justification for research and for data processing[4]. An iterative approach to governance that allows for reflection and adaptation which is important for contexts in which there is complexity and uncertainty, such as those considered here. Reflexive and responsive approaches to governance are discussed below and in more detail in Chapter 3.

Laurie (2011; 2013) argues that reflexive governance can best serve biobanks and public without the need for law. Two features of biobanking governance that are crucial to their success (for Laurie): 1. designing effective policies and 2. the role of reflexive governance as the (optimal) means of implementing policies and in ensuring biobanks deliver on stated objectives. The second point needs to acknowledge that there might there be unstated objectives, nevertheless accepted and acted upon by stakeholders or by voices dominant enough to drive a policy or decision. To mitigate this, deliberative methods can be employed during design and development. Chapter 7 discusses kinds of public involvement in research governance, including deliberation, in more detail. Involvement of publics and stakeholders must necessarily acknowledge and work with complexity. The same is true for operational and ethical challenges in governance and systems in biobanking, given the wide-ranging, complex and heterogenous nature of the field.

Knoppers refers to the need for a complex systems approach to biobank governance and describes Biobanks as a 'paradigm example' of the Collingridge dilemma: if an intervention is too early there is not enough information on which to base laws, but if delayed too long, technological advances become embedded and change is more difficult, therefore the need for the reflexive governance approach. For Knoppers, the complex systems of governance should reflect values of communalism, citizenry and convergence (2009:348). Communalism or communitarianism and citizenry refers to those values that locate individuals within their wider social groups and within society, requiring certain actions of them as citizens (Prainsack,& Buyx 2011). Here the primary group of citizens are researchers and those in biobanking who should work together for the communal good. Convergence refers to the 'meeting in the middle' the many different systems and ways of operating that exist in the field of biobanking: differing legal frameworks, research ethics set-ups and priorities for

[4] It is worth noting that although the GDPR relies heavily upon the 'substantial' public interest basis for data processing, it does not provide a definition of public interest and 'the concept of a 'substantial' public interest has no independent meaning in EU law' (Hallinan, 2020:8).

example. Convergence is related to but not the same as consensus, as it can be achieved by a moving towards shared ideals rather than having to reach full agreement or choose a 'third way' forward.

This approach is applicable to the known challenges for biobanks: longevity, diversity and uncertainty (of direction) (Knoppers, 2009:350). Longevity (and sustainability) challenges exist for the ongoing storage and management of samples and data, including how they may be shared or accessed. Diversity refers to biobank models e.g. prospective studies or repository-only and with respect to data, sample types and to the need for genotypic and phenotypic diversity. Uncertainty of direction because of the open-ended nature of some biobank research, particularly where data are re-used and aggregated with other datasets, The values outlined by Knoppers and others: communalism, citizenry and convergence are relevant to these challenges and also support Laurie's call for reflexive governance with transparent processes that will allow for uncertainty and adaptation as things change over the life of a biobank or research project by embedding flexibility and those values that support moving forward collaboratively towards a shared aim, while respecting difference rather than erasing it. This does not resolve the challenge to consent posed by uncertainty and open research, but reflexive governance is considered further in Chapter 3 and consent and the associated ethical and govenance challenges for research in Chapter 4**.** Having outlined that the complexity of the ethical and governance challenges that international biobank research poses, next we consider some limitations of legal approaches to the governance of biobanking and health data research.

2.5 Some Limitations of Legal approaches to the governance of biobanking and health data research

The scope and power of the instruments and frameworks discussed above have limitations, as does take a legal approach to research governance in general. There follows a discussion of some of those limitations and their sources. The earliest biobanking-specific law was repealed (Icelandic Act on Biobanks no.110/2000) and at the time of writing there has been no further biobank legislation enacted aside from the Biobanking Act of Finland (2012).

'Hard law' i.e. Statute, passed in a country, only has jurisdiction in that country. Just because methods or technologies are novel does not necessarily mean we need new laws. As Laurie

states, we ought ‘only add to ‘regulatory burden’ if have something ‘necessary, proportionate and likely to be effective’ (2011:351). Introducing new law could adversely impact on existing biobanks due to the tendency of law to be relatively inflexible in comparison to other forms of regulation and the possibility that any new law may be restrictive in ways that reduce the capacity of a biobank to operate ethically and effectively. It is also jurisidiction-specific, unless a supra-national instrument but that would be a lengthy and expensive process, if there were appetite for it at all (Kaye et al, 2014). Most biobanking globally is already happening without specific law(s) but under a combination of other legislation such as the Human Tissue Act, the GDPR, professional codes and frameworks.

It seems the problem may not be a legal vacuum, but too much of legislation and other kinds of regulation. Even good legislation will not provide harmonization of governance across a region e.g. the EU, which is problematic for the large-scale collaborative work that biobanks are set up to do. It could however be a starting point for mutual recognition or reciprocity in legal construction that leads to harmony. Harmonization of research ethics and governance applicable to biobanking is considered in depth in Chapter 3**.**

Governance frameworks do not have to be statutory and in the biobanking context they overwhelmingly are not. The ‘soft law’ of principle-based frameworks/guidance can be effective and several of the major research consortia e.g. GA4GH, BBMRI-ERIC take this approach. One of the challenges for developing instruments is that, typically, the end goal is known and regulation applied to ensure activity works towards that goal, but with biobanking that goal can be unknown or unknowable. Reflexive governance is therefore needed in addition to field-specific laws, because of unknown aims. Reflexive governance is not second guessing of future research activity, or ‘mechanism of foresighting’ (Laurie, 2011:352) but should be a partnership in governance with stakeholders when the future is uncertain. It can also facilitate mutual learning through the experience of adapting governance over time.

Governance should support and guide those involved to critically assess policies and practices, as well as the norms that underpin them. Reflexivity in governance gives actors the means to learn through collaboration and deliberation - adjusting all aspects as needed (See Laurie 2011; 2013 Durante, 2009; Braithwaite, 2011). It might be possible to have solely non-legal governance where there is a combination of support for compliance as the first priority and credible sanctions with practical means of evaluation and the ability to carry out those sanctions when needed. However this is not the current situation. It may not even be

viable at global scale but it is an admirable aim shared by many in the field (Townend, 2018; Boodman, 1991; Laurie; 2017, for example).

A key takeaway from the literature is that identifying gaps in legislation does not necessarily equal 'make more legislation'. The use of interdisciplinary guidelines, supporting compliance in combination with coordinated and collaborative REC review can be used to ensure 'responsible science' in the current regulatory conditions, whilst inroads are made towards clarification and perhaps simplification of the landscape through refocusing efforts into developing governance systems and frameworks that allow for reflection and ongoing development, rather than on legal instruments and the interpretation of instruments, many of which were not specifically intended for biobanking regulation. Further discussion of frameworks and the role of harmonization in supporting 'ground up' governance systems is carried out in Chapter 3. The suggestion of simplification and a move away from reliance on the law is based on the problems seen with the status quo, outlined below.

2.6 Problems with the current regulatory landscape

Fragmentation and the potential for contradiction as well confusion and lack of transparency around regulation and governance is contrary to the movement toward open science. Good governance may be a gateway to trust and the demonstration of trustworthiness in biomedical population research, aiming to support ethical and legally compliant work (Sheehan et al, 2019). Given that trust and trustworthiness are so interlinked, we might describe them together with respect to reasons for a) emergence and b) continuance. As Pettit notes, it is 'important to be clear about the reasons, in particular the good reasons, why people might invest trust in one another' (Pettit, 1995:202) both for understanding trust and trustworthiness and for predicting how they might fail. Even where the risk of actual harm is minimal, trust involves taking a risk in another sense: 'to make yourself vulnerable to the other person in some measure, to put yourself in a position where it is possible for the other person, so far as that person is a free agent, to harm you or yours'. We still recognize that the recipient of trust is a free agent and that the trustee's welfare is in their (free) hands (Pettit, 1995: 208). This refers to the risk-taking inherent in trusting another, whether or not there are some independent means of assuring or at least increasing the likelihood of their being trustworthy e.g., research ethics and governance for those considering trusting a biobank or other research entity and the people within it. Petitt highlights 'three sorts of reasons regularly associated with trust… reasons of loyalty, reasons of virtue and reasons of prudence' (1995: 209). It is the last reason: prudence that we might associate most strongly with the context of this thesis.

It may be prudential for the person seeking to be trusted e.g. the researcher to meet trust expectations, uphold professional codes etc in order to get what they need from the transaction or process i.e., access to the trustee's samples or data. We might also consider it prudent for the trustee to trust the other agent based on those expectations; to be able to rely on them behaving in particular ways that further both their interests. In order to decide who to trust we may rely in part upon signs of trustworthiness[5].

If participants and wider society can understand and be part of creating research governance then it can foster better relationships based on trust which in turn facilitates more and better research and importantly opportunities to identify and mitigate problems earlier in the process. As most biobanks are public projects or sit within publicly funded institutions, there is a stronger requirement to engage with the general public as well as the participant populations. UK Biobank and others have participant panels and some also have participant representation on ethics and governance panels and these models may be useful references in

[5] Much of what we think trustworthiness might be is determined by the expansive literature on trust. Calls for the demonstration of trustworthiness rather than relying on 'building trust' (Elstub et al,2021; Jones, 2012) have brought trustworthiness into greater focus recently. Jones asks why we have the paired concepts trust and trustworthiness, arguing that trustworthiness and trust 'are not reducible to reliability and reliance because they identify, in order to promote, a 'distinctive way that our cognitive sophistication makes it possible for us to respond to the fact of interpersonal dependency'(2012). This describes trustworthiness as competence *together with* direct responsiveness to the fact that the other is counting on you.

Accounts of trust and trustworthiness are often focused on the individual as this is the most common and meaningful type of trust interaction in daily life and because of the interrelated nature of trust, autonomy and vulnerability (Jones, 2012; O'Neill 2002; Taylor & Whitton, 2020), however we might also apply this way of thinking about trustworthiness to an institution, for example, WADA as the overarching body for doping control activity and custodian of athlete data; a biobank that I (an eligible athlete) entrust with my samples and data. In so doing, we need to consider who we might trust and whose trustworthiness is being demonstrated: Do we trust the agents that work within and make up that institution, or the institution itself? A short answer is both- we may trust a brand name without knowing anything about the individuals that work for the organisation, the NHS being a case in point (with the caveat that it is the largest employer in the UK and therefore it is highly likely that a person will know someone who works for them).

In brief, trust emerges among people based on expectations and beliefs that they hold about each other and a key one of those beliefs can be described as 'counting on'. 'Counting on' is stronger than 'expectation' because it describes a dependency (conscious or otherwise) that the person being trusted will do as they have said, or been 'counted on' to. Where the dependency is not conscious or spoken, we might only realise it exists once it goes wrong: the trustee does not behave as we needed them to (Jones. 2012). The risk type is similar for an expressed dependency, but in that case, there will usually be an opportunity to assess the level of risk before embarking on plans that may stand or fall upon a failure of trustworthiness. The level of risk and therefore the level of vulnerability it takes to trust will differ based on a range of factors including interpersonal relationships, the resilience[5] of the person trusting and a credible demonstration of trustworthiness.

starting the policy and infrastructure design for allowing research with ADAMS data. UK Biobank is a large-scale biomedical database and research resource, operating since 2006 and with half a million UK participants recruited at ages 49-60. The database is accessible to researchers and scientists globally, following an approvals process. UK Biobank data – the largest and richest dataset of its kind, contains anonymised biological and medical data as part of a large-scale prospective study. These data are derived from blood, urine and saliva samples, as well as detailed lifestyle information which can be linked to health records with consent from participants.

There is a distinction in the public mind and in regulation, between private and public goods (Middleton et al, 2018), but increasingly such lines are blurred and current regulation and governance does not always capture that blurring. An example of this is the 'spin-out' profit-making enterprise born out of academic research at a public institution. While universities have rules about shareholding and declaring interests when publishing etc the finer distinctions may not be transparent to the public and most importantly to potential research participants. The same is true for public-private partnerships where there are multiple stakeholders or contributors or funders to research. Funding and therefore funder requirements is an unavoidable aspect of doing research. It is now almost universally required that researchers declare their funding sources in publications and public-facing materials, but the role of funders in influencing research direction is often unclear. Capps describes one of the challenges of regulation in large scale biomedical research and innovation as 'the perennially challenging balance between corporate rights and individual rights' (2017:151). Goods that have a value to society and that we might conceive of as being non-monetised, or at least not exclusively so, may be at risk of becoming commodified due to the marketization of academia and research generally; the pressures exerted on researchers to achieve both income and impact. Capps claims that partnerships between organisations that seek to produce public goods and those that disrupt that aim (by the capture of knowledge solely for profit) are 'imprudent' (2017:152). Large scale public engagement and empirical research into public attitudes reflects a similar view. Your DNA Your Say (100k Genomes Project, funded by the Wellcome Trust) found that members of the public in many countries were generally supportive of genomic research and would consider contributing or already contribute, but the main area of resistance was to commercial access for-profit and there was not a strong distinction between commercial-only versus commercial partnerships with public institutions. Public-private partnerships can be complex and are not well communicated in the

media therefore some ‘myth busting’ may help people make a more informed judgement about the value and risks of such partnerships, and this will inform their consent. It should be noted that it is not just the public that find the dense and fragmented regulatory landscape problematic, researchers and those associated with research activity even more so as they have to negotiate through it without clarity and with concern regarding whether they are acting in accordance with the relevant regulation, in large part because it is so difficult to establish a comprehensive picture.

2.7 Conclusion

This chapter has discussed some of the central instruments and contexts relevant to large scale international research bio-banking and research using genetic and other kinds of biomedical data, illustrating the complexity and lack of coordination in the current regulatory landscape. The number and range of laws, codes, guidelines and policies, regulating authorities and professional bodies is increased by the multi-disciplinary nature of the field and by the fact most regulation of bio-banking is at national and not international level. One of the most important and influential international instruments applicable in this context is the GDPR and its impact on data protection, sharing and eventual destruction was considered in detail. The GDPR does not specifically mention collaborative biobank activity but one of the biggest research consortia in Europe - BBMRI-ERIC - exists to standardise operational practices and harmonize governance in order to facilitate international biobank research, having national nodes and a dedicated ethics branch. Another multinational project on the governance of bio-bank research is the GA4GH. The chapter discussed how such multi-national governance frameworks and consortia can facilitate ethical research and the production of the public goods of research while recognising their shortcomings and the need for further work on pluralistic approaches. Key aspects of ethical data-based research include privacy and data-protection but to focus entirely on these (alongside consent where it is required) is to miss some of the more nuanced challenges such as the right to participate and the obligation to share benefits from scientific research.

Participants are increasingly demanding of greater transparency and input into production of research. Some researchers may welcome this as one aspect of increasing engagement and uptake and to increase retention and therefore sustainability of longitudinal projects that require multiple contributions of data and samples over time. Further discussion of engaging

with participants and public can be found in Chapter 7. There is much work to be done to ensure that population biobank governance as it sits within the biomedical research regulation landscape is fully fit for the purpose of supporting research progress whilst protecting participants and promoting fairer sharing of benefits. Taking an optimistic approach, we might consider the lack of clarity and the fragmentation of regulation and governance tools that currently frustrates the biobanking community as also offering opportunity and motivation for the creation of stakeholder-led harmonization of governance and practice. This suggestion is based on the need for greater clarity regarding the norms and concepts that are foundational to governance and regulation, and the intersection of clarification seeking with harmonization efforts. Harmonization is a strong theme in both biobanking and anti-doping, with ADAMS at the intersection of the two. The following chapter is a critical discussion of the concepts that underpin harmonization and offers some clarification of those components and the potential benefits of harmonizing approaches to ethical governance of research for global biobanking, and as it might apply in the case of WADA- ADAMS.

3 Harmonization of ethics and governance for research

3.1 Introduction

The significant growth in population biobank research and the aggregation of large datasets over the last couple of decades was spurred largely by an increase in the speed and accessibility of technologies for the collection, storage and processing of genomic and data-based research along with more efficient and scalable collection and storage techniques. This has led to the development of multiple international biobanking consortia amid the ever-increasing demand for bio-data. In light of this growth and ongoing innovations, consideration of how to bring together such data in a meaningful way, including but not limited to ethical and political considerations, is needed. One key aspect of international biobank research is the harmonization of governance in conjunction with operational standardization.

This chapter interrogates the concept of harmonization and some key related concepts such as responsive governance, as applied to the governance of international population biobank research. Biobank governance includes results interpretation and reporting, benefit-sharing, biobank closure, data access and use decision procedures and accountability processes. First, an outline of the reasons for working towards harmony across jurisdictions is presented. Secondly, we examine key concepts relating to harmonization before, finally, critically discussing aspects of ethics and governance in biobank research that are the proper object of harmonization including the associated benefits and challenges.

3.2 Harmonization in the Literature

Harmonization is a term used extensively throughout the scientific and ethics literature on biobank research (e.g. Tasse, 2013; Knoppers; Dove, 2015; Chadwick & Strange, 2009) with a focus on the potential for harmonization and interoperability under shared research governance and ethical oversight to respond to the problems arising from piecemeal regulation and conflicts between differing national (and state in federated countries) instruments. The World Anti-Doping Agency (WADA) makes explicit reference to the role of harmonization in global anti-doping efforts, here in reference to the World Anti Doping Code (The Code): ‘The purpose of the Code is to advance the anti-doping effort through universal harmonization of core anti-doping elements’ (WADA, 2021).

Harmonization is a legal concept that has its etymological roots in music (Boodman, 1991; Dove, 2015; Indech; Tasse 2013). While there is no officially recognized definition, Boodman offers a useful shorthand: 'Harmonization is a process in which diverse elements are combined or adapted to each other so as to form a coherent whole while retaining their individuality' (Boodman 1991;702). The substance and boundaries of what is to be harmonized, and how, are not defined by saying that they are (to be) harmonized. Although Harmonization is quite widely discussed and applied in global research and in anti-doping efforts, it has never been subject to in-depth interrogation beyond legal analyses. Harmonization is a concept acquired from comparative law (Boodman, 1991) and applied to research ethics and governance (Knoppers, 2014) as a way to enable collaborative efforts across multiple settings:

> 'Harmonization is often used in technical fields where standardization procedures are an accepted mechanism, and this is applicable to the field of biobanks. On the other hand, in conceptual fields such as ethics, harmonization is questioned, particularly regarding whether it is desirable or possible without distorting the underlying principles on which ethics are based' (Rial-Sebag & Cambon-Thomsen 2012:119).

As Rial-Sebag and Cambon-Thomsen note, there are two aspects of procedures that could be the object of harmonization with respect to biobanking. The first is technical: it refers to the standardization of technical procedures, nomenclature, and variant interpretation where it could be desirable in order to achieve the compatibility necessary to usefully share and aggregate data for the added utility of that new grouping of data. This seems straightforward, for example, with respect to genetic diseases that can now be investigated due to advances in sequencing technologies and the significant ongoing expansion of available relevant datasets. Nevertheless, there still exist challenges here. For example, some important operational standards remain challenging, such as the classification of genomic variants. The development of international standards is something that scientists and clinicians across the world could perceive as mutually beneficial, even where the economic drive to commercialize such data might be in tension with such agreement.

With respect to the second object of harmonization that they point out, conceptual and ethical applications, things are much less clear. The present case, which we will consider in depth, with respect to harmonization is in the context of anti-doping policy and practice. It seems to span the two categories that Rial-Sebag and Cambon-Thomsen distinguish, conflating the

clarity of the distinction. Moreover, the harmonization of policy linked to anti-doping data is a distinct one: potential biomedical research uses of data arising from anti-doping activity in elite sports. This case is significant because it sits at the intersection of medical and non-medical population research. A careful consideration of this distinctness is merited.

A selective sample of elite athletes, performing at the highest level, belong to what is called a "Registered Testing Pool" (WADA 2021)(RTP). These are usually athletes considered to have the potential to win national and international competitions. Their status on the RTP may be controlled by the respective National Anti-Doping Organisation or the relevant international sport federation. The RTP athletes must provide certain geolocalisation data (Borry et al, 2017) and biological samples as a prerequisite to compete in high level sports.

This data is collected in the WADA biobank widely referred to as ADAMS: Anti-Doping Administration and Management System (WADA, 2021). It holds the whereabouts data, biological profiles of each athlete so registered, and also other information such as whether the use of prohibited substances have been requested/approved in the treatment of legitimate medical conditions.

The fact, however, that the agreement with the data and sample protocols is mandated within the anti-doping system raises questions concerning the validity of the primary consent and following that, any consent to secondary research uses of those samples and data. These questions are explored further in Chapter 6. The ADAMS database is a global biobank in reach and the owning organisation (WADA) is a global one that expressly claims to take a harmonized approach to the governance and operational conduct of anti-doping at all levels of sport (WADC, 2021). This combination of factors creates a uniquely challenging context, and an equally unique opportunity, to examine harmonization concepts.

Despite requests by scientists and consideration by the WADA Ethics Expert Advisory Group research uses of ADAMS outside of anti-doping have not been approved. It is therefore timely to interrogate whether current governance and methods of development of WADA governance ought to be adapted (or novel means introduced) for the granting of dual use of the samples/data for specific, e.g., biomedical research, purposes.

3.3 Harmonization and regulation

It should be noted that harmonization is not used in the strictly legal sense here (Peters & Schwenke, 2000). A primary focus for harmonization efforts in biobanking is data sharing,

due to the need to collaborate on increasing the scale, scope and heterogeneity of data sets to increase their utility and range of applications.

Data sharing is a priority for researchers, institutions and governments because much population research would not be achievable without international cooperation and access to scaled-up datasets e.g., those have been aggregated together from multiple sources to form large volumes of data to facilitate statistical analyses. A particular area of biobanking that is reliant upon data sharing is rare disease research, where the cohort numbers per nation are often too small to be able to conduct effective investigation at a single population level (e.g., Gainotti et al, 2018).

As discussed in Chapter 2 much governance and regulation of international biobanking is located in 'soft law' from scientific bodies and international guiding bodies such as UNESCO, Council of Europe and others. Notably there are no internationally binding instruments specific to biobanking. As Reichel points out, the issues raised in biobanking can be sensitive, including but not limited to DNA, genomics results, and health information, which 'makes it difficult to develop common binding rules' (2015:166).

There has been a tendency to attempt to resolve moral conflicts by recourse to single or universal systems/ principle-based frameworks. This approach has historically failed to account for or even acknowledge the diversity of contexts and conceptual bases. Doing so is both necessary for ethical justification but also for pragmatic reasons with respect to the range of settings in which guidance, regulation and ethical rules are to be applied. The dominant approach to biomedical ethics in the west is derived from the work of Beauchamp and Childress (8th ed, 2013), and is often referred to as principlism. It sought to bring together the variety of ethical norms that confronted clinicians by providing four very general ethical principles: respect for autonomy; beneficence, non-malefience; and justice. Though it was what they described as a "mid-level theory" it drew upon moral sources from both deontology (duty-based ethics) and teleology (specifically consequentialist ethics) and its original aim was for it be a universal framework to guide ethical decision making in medicine.

The principalist approach to healthcare ethics of Beauchamp and Childress conceptualises autonomy based on understanding (of relevant concepts and information), intentionality and freedom from control (Beauchamp & Childress, 2013). This model demands respect for autonomous choice, belief and actions and encourages a supportive and constructive respect

of autonomy in others and is one of a number of models for autonomy in a vast literature. Autonomy is an integral aspect of consent and other kinds of decision-making and therefore next I offer a brief overview of key accounts of autonomy with the most potential relevance to the contexts and actors that are the focus of the thesis.

The Kantian concept of autonomy is concerned with rational agents, whose moral principles are formed autonomously and without internal or external constraint. A person is autonomous if she acts according to her own values or as Coggon states '…an agent recognises them as his values, and seeks to act in accordance with them' (Coggon, 2007: 643). The person is autonomous if her direction expresses her
current desire, her best desire, or her ideal desire (Coggon, 2007: 461).
Procedural autonomy conceptions focus on the development of desire and include Dworkins description of critical reflection upon first-order preferences. Procedural autonomy involves the adaption of opinions following internal, critical reflection of the hierarchy of preferences which allows the retention of autonomy in the face of oppressive social forces.[6] Critical self-reflection, followed by action or choice is described by Friedman as the defining characteristic of this procedural autonomy, which can encompass a choice to disrupt or to comply with cultural and social norms. Procedural autonomy may be criticized for a lack of consideration of internal morality or rationality, and the potential underestimation of the ways in which desires develop through socialisation. Next we consider a conception of autonomy that attempts to account for influences and constraints on desires.
Substantive autonomy describes autonomous action driven by values that are determined by normative constraints. Substantive concepts of autonomy focus on external and relational influences on desire. The inclusion of normative competence, whereby norms are incorporated into decision making, raises issues of responsibility and objective morality (Stoljar, 2006; O'Neill 2002; Friedman, 2003). Diminished autonomy as a result of being undermined by of social forces and/or normative constraints is brought to the fore in feminist and psychological accounts of autonomy. A concept of self-determination according to personal motives and values, envisions a moral law formed by free agents, independent of influence by external or personal interest, such as relationships or emotion. Due to a denial of the value of social relationships some feminist scholars have responded to the shortcomings of traditional accounts of autonomy, by developing alternative frameworks such as relational autonomy. Relational autonomy models consider interdependence, social context and

[6] See S6.4 for a discussion of voluntariness and coercion

relationships with others as crucial to formation of opinions and decisions, rather the traditional independent model of an autonomous agent. Feminist approaches consider oppression and the eroding of autonomous capacity, from a gender perspective and draw on the ethics of care to centre relationships rather than individual rational desires, seemingly isolated from the connected world in which agents exist (Held, 2015; Stoljar, 2006). Relational approaches have been increasingly considered in non-feminist academic analysis of paternalistic health and research practices over the last few decades (Stoljar, 2006). These approaches examine the influence on autonomous decision-making by excessive deference to the opinions of others. This includes adaptation to available choice options formed as a result of internalised social oppression and in some cases tensions between practices perceived as oppressive or coercive by the individual, but taken on because they are a strong norm in their society or culture. Causal or constitutive concepts of relational autonomy examine autonomy in view of social relations and constraints upon choice making. The relational account of autonomy is most useful for the consideration of heterogenous populations across multiple legal jurisdictions and cultures, particularly in respect of efforts to collaborate and move towards shared goals from differing start points. Harmonization may offer a means to facilitate forward movement of this kind, incorporating a relational approach and developing iteratively to encompass the range of actors and viewpoints. Next we consider some features of harmonization in the context of research ethics and governance.

3.4 Features of Harmonization

Harmonization creates a relationship but does not define the elements of that relationship, nor how exactly they relate: 'the nature of harmonization is dependent conceptually upon the nature of its components' (Boodman 1991:702).

In law, political and legal sovereignty mean that in theory one might harmonize. seemingly identical laws from different jurisdictions. Harmonization with respect to governance refers then to both processes and substantive content that are brought together. Thus if two countries have identical regulation for consent to further uses of biological materials for example, they may mutually recognize the other without loss or conflict. In such circumstances no explicit harmonization is required. It is certainly foreseeable, however, that the practice or application of a regulation may differ to some degree in each location. If we aim to develop a principle-based framework that supports some variation in local contexts then this may mean that principles are justifiably applied differently. What

would be critical is to reach agreed boundaries for the extent and kind(s) of permissible variation. A highly prescriptive code of action would in principle clash with variations in practice or prioritization. Equally, if a purportedly harmonized approach allows too much scope then it risks being worthless. Thus, a key aspect of harmonization work must focus on the deliberative design of the framework(s). In order to achieve this, clarity regarding what precisely it is that is to be harmonized is needed.

Boodman describes four related features: i) the diverse elements to be harmonized, ii) the rationale for or problem to be resolved by harmonization, i.e., whether and how diversity is problematic; iii) the ultimate goal of harmonization; and iv) the method by which this goal is to be achieved. (1991:708). If we accept this as a workable definition for the operationalization of practising harmonization then it will be necessary to carefully evaluate each feature in order to justify harmonization in relation to ethics and governance for international population scale biobank research and specifically for WADA's ADAMS resource.. It is necessary to determine the authoritative sources for the principles that might support harmonization of ethics and governance for population biobanking. One option that might be aimed towards is consensus from the international community, in order to avoid simply imposing the greatest will, although there is no guarantee that this approach would safeguard against the imposition of dominant parties' wishes due to the geopolitical relationships that inform such processes. 'Harmonization is a value-neutral concept' (Boodman 1991:702) and cannot be an end in itself, but is a mechanism for organizing and forming coherence from difference. The neutrality, goodness or otherwise is derived from the context in which the harmonized variables exist. In the case of harmonization of ethics for population-scale research a good may be the (potential for) increased societal benefit from international collaboration that is facilitated by harmonizing ethics approaches.

Different voices, real or metaphorical, are necessary but not sufficient for harmony. After all, harmonies can be discordant. In general, however, the term has positive normative import. It implies something agreeable, concordant (Tasse, 2013). Often when the term harmonization is used in discussion of law, regulation or technical standards implies that to harmonize is a good thing. The claim made in this thesis therefore is that harmonization is not a value free, neutral term, but an ethical stance in itself. This is in opposition to the position taken by Boodman, who claims that 'Harmonization is a value-neutral concept' (Boodman 1991:702). He also argues that and harmonization is not an end in itself, but is a

mechanism for organizing and forming coherence from difference. The neutrality, goodness or otherwise comes from the wider context in which the harmonized variables exist.

It may be that harmonization in biobanking governance, harmonization, does not create new ethical issues. Nevertheless, there are unresolved elements that are still challenging, such as secondary or re-use for purposes outside those originally consented, of samples and data. A newer aspect of considerations of ethics and governance worthy of consideration might be sustainability or viability of a resource or network in the longer term. After a decade of major biobank projects, we have seen the proliferation of biorepositories and the data they produce, as well as an increase in aggregation both of same data types and combining phenotypic with genotypic data (Jones et al, 2017). The latter data type is noteworthy in terms of clinical utility as it arises frequently from the linkage of biobank product with health records and other health related data. Classification of what can be considered health related data is wide and largely undefined, requiring further investigation, but outside of the scope of this chapter[7]. Returning, therefore to the normative significance and challenges of it is also noteworthy that in the context of harmonization of comparative law, Boodman argues that "harmonization" is a meaningless concept because parties can communicate about law across jurisdictions because the systems 'share an intellectual and jurisprudential tradition' and therefore no harmonization is needed in order to facilitate inter-jurisdictional communication (1991:707). While this may be true of legal traditions, it is far from clear that this observation has implications for biobanking governance and its operation. The following section, therefore, considers biobank harmonization in practice.

3.5 Harmonization in practice

BBMRI ERIC is an EU-wide network of over 200 associated organizations, most of which are biobanks from more than 30 countries. BBMRI-ERIC was established in 2013 and focused on creating practical harmonized governance as opposed to binding legislation for reasons of time and flexibility, as well as the challenges of influencing the development of state legislation in all member countries. Stakeholder-led frameworks that complement existing guidance and regulation were chosen as the most effective method for developing

[7] The focus of this chapter is, however, on the relationship between data, agents and harmonization of approaches, to data management, sharing and benefit distribution, rather than on the fine definition of data types

harmonized procedures and principles for collaboration and data sharing. There is economic and political reasoning for collaborative EU research structures, but they are also a means of skill and resource sharing towards a common goal (BBMRI-ERIC, 2021).

BBMRI-ERIC have been critical of confusion in biobank-relevant guidance. For example, the confusion arising from differences between the GDPR and European Data Protection Board (EDPB) (Vlahou et al, 2021). A key function of BBMRI working groups is their critical insight into the relevant regulatory instruments and their interpretation in the biobanking sector of the network. Expertise in regulation, governance and the operational work of biobanking all inform the development of strategies and harmonization efforts across European biobank nodes[8]. This is reflected in the integral or composite model of administration- 'a specific feature of the composite administration is its fragmented structure' and that 'the organisation and inter-relationships between its constituent bodies vary from one policy area to another' (Vlahou et al, 2021).

BBMRI-ERIC is a heterogenous model with blurred boundaries that allows for 'soft law' and has the ability to resolve issues that could not solved by either a supra national body, or member bodies alone (Dove, 2015). Whilst such a composite approach might have advantages in richness and flexibility, the lack of overarching direction or single strategy for the network might lead to a lack of coherence in policy development and this concern is compounded by the emphasis on shared technical or operational standards. The deliberately fragmented structure seems at odds with critique of the 'fragmented regulatory landscape' (Laurie, 2011; 2017) however there are key differences; foremost that the independent organisations that make up BBMRI are members due to their united aims, and to their mutual benefit, whereas the fragmentation referred to in critiques of the regulatory terrain is a result of instruments and codes being developed without coordination and, importantly, usually not directly for biobanking. There are differences and points of contention within the BBMRI network, as to be expected in a large multinational network, however difference and even disagreement does not equal failure. Indeed, one of the strengths of a harmonized rather than standardised system should be the flexibility and room for difference without loss of efficacy. As Boodman notes, harmonization as it is described in law has an 'utterly flexible and

[8] Each BBMRI member country nominates a 'national node'. For example, the UKCRC Tissue Directory and Coordination Centre is the UK's National Node).

indeterminate nature' (1991:706). The role of difference and other key concepts that underpin harmonisation including principles, plurality, recognition is explored further on.

The heterogeneity of organisations and funding sources that make up the biobanking field is another factor that supports a harmonized approach to ethics and governance. Some of the types of organisations and their relationship to global governance are explored below.

Many population biobanks and networks that utilise them are publicly funded and may operate as a registered charity (UK Biobank), as part of an existing public institution (UCL GCRC Biobank) or as a public-private partnership (100k Genome) (Caulfield et al 2014). Private repositories also exist but are fewer in number and they are outside of the scope of this thesis, which is concerned primarily with publicly funded work including public-private partnerships. This is because of practical limitations but primarily the public interest justification for research and the ethical challenges that arise from it. Genomics England was set up by the Dept of Health & Social Care (DoH) to deliver the 100,000 Genomes Project. Genomes England is a registered company, but one solely owned by the DoH and with profits returned to the health service (UKBiobank). The range of composition and kinds of activity that take place just in the examples given indicates some of the complexity of the field and the need for structures or organisations that can facilitate ethically justifiable collaborative work.

The Global Alliance for Genomics and Health (GA4GH) is a 'policy-framing and technical standards-setting organization, seeking to enable responsible genomic data sharing within a human rights framework' (GA4GH). It highlights, and is guided by, Article 27 of the 1948 Universal Declaration of Human Rights. Article 27 guarantees the rights of every individual in the world 'to share in scientific advancement and its benefits' (including to freely engage in responsible scientific inquiry), and at the same time 'to the protection of the moral and material interests resulting from any scientific...production of which [a person] is the author.'

In 2014, the GA4GH adopted the Framework for Responsible Sharing of Genomic and Health Related Data (the 'Framework'), which sets forth a harmonized and human rights approach to responsible data sharing in accordance with Foundational Principles and Core Elements (GA4GH, 2014). based on Article 27 of the 1948 Universal Declaration of Human Rights (UDHR). Article 27 guarantees the rights of every individual in the world "to share in scientific advancement and its benefits" (including to freely engage in responsible scientific

inquiry), and at the same time "to the protection of the moral and material interests resulting from any scientific…production of which [a person] is the author." (UDHR, 1948) .
This approach is a human-rights based one that attempts to develop principles for universal application. Some key principles are given below:

> 'The value of this Framework is that it: offers political and legal dimensions that reach beyond the moral appeals of bioethics and provides a more robust governance framework for genomic and health-related data sharing; speaks to groups and institutions, not just individuals; stresses the progressive realization of duties; and urges action by governments, industry, funders, publishers, and researchers to create an international environment for responsibly sharing data' (GA4GH, 2014).

> 'This Framework will be elaborated by subsequent Policies… on particular issues such as ethical governance, consent, privacy and security. The stated aim being that policies and instruments be developed based on the framework and related policies… such that they become the tools that approval entities, recognized by different jurisdictions, will turn or refer to for guidance. Here the Framework recognizes the need for flexibility and adaptation in local contexts whilst retaining core principles that inform the detail' (GA4GH, 2014).

Most modern national laws are based on an ambition to adhere to a common set of core principles derived from the declaration of human rights and international declarations such as the Declaration of Helsinki (Klingström et al, 2018). This means that even if there is little legal harmonization between countries, there is a strong case for researchers to argue that institutional review boards should take into account decisions from review boards in other countries, in a soft version of a principle of mutual recognition (Klingström et al 2018). Mutual recognition is a principle primarily associated with European Law, specifically the operation and governance of the EU and its 27 Member States. Mutual recognition requires states to recognize each other's laws and jurisdictions and to avoid 'double burden' where legal demands clash or duplicate in both states either side of a border. The reason for mutual recognition is the lack of substantive harmonization of European statutory instruments and associated systems (Möstl, 2010). The concept of recognition is applicable outside of law and a relevant example, that of Research Ethics Committees (REC), is discussed below.

A practical example of recognition, in this case of Research Ethics Committee equivalency, is seen in the efforts of GA4GH in order to prevent or reduce duplication of ethics procedures

and move towards a more consistent approach to oversight in different locations. This is particularly important where samples and/or data being shared between places not only to ensure that operational standards are translatable or even unified, but that RECs are considering the same issues or at least using the same terms to describe the same things even where the things being considered may differ between contexts/settings. It is not necessary to have to go through a REC approval process identical to colleagues in the US for example, but in order to share results or aggregate data to better explore a particular condition or variant, we must share terms and meanings. Scientific standards and codes of conduct, such as laid out by ISBER, BBMRI provide the technical interoperability necessary for meaningful cooperative research on an international scale. Such standards are essential to the integrity and quality of population research, however they do not account for differences between contexts and therefore responsive, harmonizable governance that is able to accommodate context-specific needs and complements technical standards is needed.

Harmonization efforts

In 2014, the GA4GH adopted the Framework for Responsible Sharing of Genomic and Health Related Data (the "Framework"), which sets forth a harmonized and human rights approach to responsible data sharing in accordance with Foundational Principles and Core Elements. The framework is based on Article 27 of the 1948 Universal Declaration of Human Rights. Article 27 guarantees the rights of every individual in the world 'to share in scientific advancement and its benefits" (including to freely engage in responsible scientific inquiry), and at the same time "to the protection of the moral and material interests resulting from any scientific…production of which [a person] is the author.' This approach is therefore to be a human-rights based one that attempts to develop principles for universal application. Explicit reference is made to human rights and their basis in human dignity, though as with much rights-based discourse, no clear definitions of terms is given. There are operational and technical aspects of biobanking, as well as ethical and governance, that should reflect a human-rights based framework, in particular Art. 27, and sustainability is one of those, outlined briefly below.

Sustainability is a real concern for all those involved in population research, sustainability of biobanks and of collaborative research endeavours that require biobank samples and/or data. Sustainability referring to the power and infrastructure demands of large-scale data usage is

also of increasing concern, and although the former type of sustainability that has been a greater focus for developing research ethics and governance, more recently moves to include the latter in biobanking and research ethics discourse have increased (Samuel & Lucivero, 2020). Many of the earlier concerns about storage capacity have been resolved for now by the use of cloud computing and the advent of quantum computers, neural nets over the last decade. New technologies and the increased ability to access data remotely are key factors in providing exponentially greater computing power so that we might analyse ever greater quantities and complexity of data and developments continue apace. This offers a sense of just how quickly data sharing and access on a global scale has become a necessity for population research, and the expanding potential global applications.

Creation of new technology-specific laws alone is unlikely to be a sufficient response to these new challenges.

> 'Public collaboration and engagement are essential components of values-based governance. Just as importantly, regulatory instruments need to be regularly evaluated to ensure their legitimacy, responsiveness, and effectiveness' (Nicol, McWhirter & Dickinson 2016:411).

Changes will be needed if existing laws cannot be applied in fitting ways that reflect societal and research norms. Integrating public or relevant interest group input into developing harmonized ethical governance for population biobank research may help to increase nuanced understanding of public concerns. A topic that illustrates the potential advantages of inclusive research development is public and private partnerships (PPP) whereby the assumption that the public do not like commercial involvement in research is challenged by responses that broadly show acceptance of industry partners, so long as there is also public benefit (Middleton et al, 2018). The relationship between public engagement and involvement, and governance, is explored in Chapter 7. In addition, demonstrating trustworthiness of the institutions concerned can be supported by developing governance in the public eye. It should be made clear, however, that this is not a justification for public opinion driving policy, but a proposal for co-producing governance where appropriate.

> 'Harmonization is often used in technical fields where standardization procedures are an accepted mechanism, and this is applicable to the field of biobanks. On the other hand, in conceptual fields such as ethics, harmonization is questioned, particularly regarding whether it is desirable or possible without distorting the

> underlying principles on which ethics are based' (Rial-Sebag & Cambon-Thomsen:119)

Standards are not without merit in research ethics- HUGO recommendations for profit discharging from private companies for example. (HUGO, 1998). It must be clear, however, that standardisation and harmonization are not synonymous. The music analogy employed by many to illustrate this point (Tasse, 2013, Boodman 1991; Chadwick & Strange 2009 and others) reiterates that the move towards harmony is not one towards a single 'note' or method but a combination of 'voices' or standpoints that create a new approach to governance, reflective of the contributing parties. Harmonization is perhaps most usefully viewed as a process, rather than an end in itself. It is the results of harmonizing, for example, regulations or governance approaches across jurisdictional and geographic boundaries, that matter; that systems are better able to work in ethically justifiable and practical ways by accommodating difference within systems that share core norms and aims.

Much of the existing governance and legislation that applies to population biobanking is based on the concept of sovereign states and does not account for the integral collaboration and sharing of data and, less often, samples across borders. Even where robust governance exists for local biobank practices, and particularly where that governance is legislative, sharing internationally is complex and difficult or even prohibited. The GDPR is an example of harmonization of data sharing governance via legislation, though all EU member states must automatically comply without having to draw down into national law, the details of research exemptions and data sharing are able to be determined by individual states. Therefore sharing between states could still be problematic even though data governance is nominally harmonized. The GDPR applies outside of the EU to any data held on EU citizens anywhere in the world and has generated a wealth of legal scholarship and differing readings (See Yeung & Lee, 2021; Vlahou, 2021) demonstrating the difficulty and complexity of drafting such a wide-ranging instrument and in particular one that allows for a range of local interpretations.

Another challenge to the reliance on national legislation? as a defining characteristic for shared ethical oversight and data sharing is the ever-increasing power of supranational technological companies and enterprises that have no single geographical location but wield global influence. Attempting to develop universal principle-based ethics that prescribes action has been criticised as lacking the subtlety and fluidity required to be usefully applied

across multiple and diverse settings. As Benatar observes this can lead to 'agreeing on the lowest common denominator' in order to move forward (2005:207).

We cannot assume that harmonization and research ethics and governance are automatically compatible. As Boodman observes in the context of law, it is 'essential to examine its constituent elements- harmonization and law- without assuming they are necessarily compatible, complementary or meaningful together' (Boodman 1991: 700). The multi-functional and multi-disciplinary nature of biobanks brings considerable complexity (Rial-Sebag & Cambon-Thomsen, 2012). Careful consideration of the interplay between law, ethics, professional codes, technical standards and politics is required to evaluate how principles and instruments may be translated into shared action.

3.6 Harmonization and responsive (reflexive) governance

O'Neill develops a critique of principles aimed at universal application as being either too broad as to have meaning, or too narrow/rigid to allow the interpretation needed for them to be practical. These challenges create difficulty in moving from principles to action. In order to be action-guiding, principles must be coupled with practical judgement (O'Neill, 2018). Practical judgement is a necessary supplement to, but not a replacement for, practical (ethical) principles and it is this practical judgement, described by O'Neill and drawn originally from Kant, that provides contextual, situation-specific expertise or judgement in a principle-based system. Acknowledgement of this stance, ethical governance can guide action seemingly quite diverse circumstances or cases using the same sets of rules or principles.

If a scientific study is ethically permissible in place x, but not in place y, what, if any, special limits might that place on what can be done in that study? Suppose that the work is not permissible universally, and that some but not all aspects of that particular research is permissible? How do international researchers on such a study proceed? Perhaps what is important to consider is the nature and impact of the non-universally approved elements. Orentlicher (2012), for example, claims that differing ethical standards exist and may be justifiable. For example, the level of compensation that a participant may receive before it is considered to be 'undue inducement' may vary substantially between countries. We must also acknowledge that there are significant differences within populations in terms of wealth and empowerment in the research setting. Not everyone in a 'developing' country is poor, but equally there are huge disparities in income and therefore potential susceptibility to financial

or perceived therapeutic gain as coercion in developed countries too. The complexity of our societies requires a more sophisticated approach than one-size-fits-all for a given geographical location. Local requirements can be encompassed in a scheme that is harmonized by and for its stakeholders.

Researchers are held to higher ethical standard than clinicians because 'research often entails the taking of special risks' (Orentlicher, 2012: 506). There may be an expectation of benefit from taking part in a research project, particularly one deemed to be 'risky'. This is not the same as therapeutic misconception, though it may include it. Therapeutic misconception is a term, first used by Applebaum et al (1982) and used in health research that refers to the conflation of research with treatment or 'therapy' by the participants. Substantial research supports this (see for example, Lidz & Appelbaum, 2002; Henderson et al, 2007). Therapeutic misconception is problematic because it can lead to someone taking in part in research that they may not properly have understood and thus not consented to without the perception of clinical or therapeutic benefit in their own mind. This may be a greater risk for patient groups or for those who contribute to biobank research for a specific condition or disease but keeping the risk in mind can support efforts at improving clarity and transparency in general.

How can we know when harmonization is working? Regulation and governance should be collaborative and capacity-supporting, with punitive measures at the far end of the scale of actions (Braithwaite, 2011). Harmonized governance frameworks need to be responsive to academic, legal and practice developments over time, containing provision for adaptation and iterative development based on responding to developments e.g. in technologies or needs.

Braithwaite's (2011) 'Responsive regulatory pyramid' originally developed in organizational theory and is based on restorative justice work, used to shape responsive regulation thinking as a shift away from reliance on reactive legal instruments and other forms of governance that were not sufficiently flexible or context-specific. It offers a practical model to support complex systems of governance and is based on identifying challenges and then attempting to build mitigations into processes, rather than waiting for a problem to arise before considering how to respond. Braithwaite describes the pyramid idea, as a means to provide a context for the pluralist, dynamic, deliberative quality of the other features of responsiveness (See S3.7).

Signaling is a key part of developing effective, responsive governance, using signals that should be credible but not aggressive i.e., it should be believable that consequences would follow unjustifiable transgression but not in a threatening or coercive sense. Signaling is a way of holding actors responsible for their actions and enabling communication of challenges *and* resolutions. This model is intended to operate on by stakeholders applying lessons from issues, challenges and failed attempts, informing and facilitating successive iterations of governance. In this kind of approach, resistance to existing structures can be framed as the opportunity to reconceive and then alter principles or other aspects of a harmonized system, as needed. Sanctions are available for transgressors and should be used where necessary, but a focus on proactive support for parties (who are aware that sanctions also exist) may be more effective than a system either with no enforceable power, or that has sanctions as a first resort. Rewarding positive behaviours is not a new concept, but empirical work is needed to understand how it may support effective research governance and in particular harmonized approaches for global research.

States and regulatory bodies can support capacity-based models, meaning those that presume stakeholders are capable of making ethical decisions and effecting change with support needs ranging from none through dialogue through to sanctions, that support the development of the capacity where needed, rather than tightly enforcing a particular method and taking a more immediately punitive approach to failure and/or divergence from the status quo. This provides a means of working towards harmonizing by requiring actors to meet the best practices/higher standards achieved in their field, rather than creating them anew. Some aspects could also be written into law to support non-statutory frameworks if necessary, but this would still be practice-originated rather than imposed from the top-down. Such an approach is not simply about just legality or compliance but demonstrating the values that are considered key to ethical research and to civil society more generally, acknowledging differences, for example in conceptions of individual autonomy, but that there are core values held in common, effectively describing a combination of personal morality and regulated (research) culture working towards being harmonized across different settings.

3.7 Responsiveness and governance

Here we return to the question of plurality and universality and while this discussion does not attempt to fully resolve which is the correct basis for ethics in general, it does support a

pluralist approach to governance and ethics for research biobanking[9]. The aim of interrogating some of the core concepts in harmonization and accompanying responsive regulation and governance is to open up some of the hard questions about what these terms mean and what they are able to contribute in the context of population scale biobank and biomedical research, and importantly, what they cannot. To be responsive in governance is to be able to anticipate and react in a timely manner, retaining inclusivity and flexibility without being subject to whims. The response is to events and shifts in thinking, regulation, but may also be to observed needs or to explicit requests for change from stakeholders. An example of future-facing ethical enquiry that can support the development of context-specific governance and ethics is the work of the Nuffield Council on Bioethics, in the UK which has onging 'horizon-scanning' work as well as responding to major events and ethics challenges as they arise[10]

Dialogue is a means of treating agents with respect by faciliating expression and listening, and may help to avoid individual coercion by ensuring that all relevant parties are able to contribute. Dialogic or discursive approaches as part of governance structures may also act to increase compliance and legitimise stronger punishment or sanctions should they be needed. This is because it seems more acceptable to move to sanctions or tighter controls following attempts at resolution or agreement using discursive methods than to impose punishments as a first line. This may be even more the case where those sanctions have been decided with the input of those subject to them, through dialogue and iterative development. Restorative or reparative work may sometimes be required, where harm or significant wronging has occurred, however it may not be possible to fully engage with restorative work following transgressions, without some coercion. It seems reasonable to assume that few organisations would put themselves under a spotlight unless the alternative was a significant sanction or punishment.

Responsiveness should be considered across time as well as context and geography- norms and expectations shift in society over time but also over the life-course at an individual level and therefore all frameworks and regulation ought to be conceived as living documents. This does not mean making change on a whim, but monitoring and evaluating the regulation, working in the context and with societal norms more generally to proactively identify where adjustment may be needed. This must be accompanied by having the capacity to make and

9 See S 3.9 Pluralism and harmonization
10 https://www.nuffieldfoundation.org/research/nuffield-council-on-bioethics

implement those changes. Stakeholder buy-in at all stages will make this much more possible and mitigate the known problem of producing redundant or immediately outdated regulation. Ongoing 'listening' from regulators is vital to spot potential problems and be able to support timely responses. Braithwaite characterizes law as reactive, whereas regulation and governance ought to be proactive: A 'normatively justified responsiveness to context' (Braithwaite, 2011). This seems potentially to exclude law from a package of reflexive and responsive, harmonized governance for international research, but that is not a realistic prospect and therefore a compromise is needed, drawing upon a combination of ethical and governance elements to be harmonized.

3.8 Elements to be harmonized

This section briefly examines some key elements to be harmonized in biobank governance and ethics: Consent; REC review and data sharing. Each of these key elements is considered below.

Consent- data aggregated from multiples sources may have been collected with different consent models, or no consent at all, either because it was not required by local research ethics due to anonymization or other reason for exemption, or for older collections where practices around data collection were less strict.

Conceptions of autonomy may differ[11] and this affects consent to use of samples or data, but also how people perceive the results of research that is based upon their data. Here I rely upon a relational model of autonomy as it reflects the ways in which people make decisions about themselves and others in their interconnected lives[12] The communitarian turn in research reflects a potential shift from autonomy-individualistic to group benefit, grounded in solidarity and the idea of the good citizen (Harris, 2005; Jefferson et al, 2014). Communitarian or other relational approaches do not preclude individual autonomy but do not hold it as a priori, rather the good of the group or society and the relationships between actors are prioritized[13]

REC Review- For example the GA4GH recognition/equivalency framework was set up to enable mutual recognition of research ethics oversight and reduce duplication of review in order to facilitate multisite research in a fairer and more efficient way.

[11] See p51-52 for an overview of autonomy models
[12] See p51-52 for relational autonomy and p98 for relationality more generally.
[13] See p39 for a brief discussion of communitarianism and solidarity

Data sharing- As mentioned, sharing data is now integral to population biobank research due to the need for extremely large amounts and different sources of data in order to have the proper statistical power for population level studies and to examine trends, determine between multiple factors that may be causally linked to the development of a condition or diseases. There are many uses and applications of cohort or population biobanking such as UK Biobank's provision of data for the COVID-19 response which was able to happen at speed due to the existing data and to the large number of participants already in the cohort and willing to contribute[14]. A common theme, however, is the need for massive amounts of data that can often only be achieved through aggregation of multiple research cohorts and studies. This places significant demands on the need for data sharing that is both ethical and efficient and is an important aspect of the motivation for developing ethical and governance structures that can effectively manage the scale and complexity of international data-based research. Population biobanking requires sharing of data, or provision of access via e.g. Trusted Research Environments (TREs) where data are not removed from the biobank or database but research access is allowed under controlled conditions. Advances in technologies for securing and remotely accessing data are somewhat shifting the focus of governance and ethical oversight from sharing to access but the challenges for multi-jurisdictional research remain (Rahimzadeh et al, 2016; Van Schaik et al, 2014).

Chalmers et al's (2016) country-by-country review of infrastructure and governance for biobanking illustrates the variety of approaches to biobank governance. It incorporates existing law(s), legislation development, national governing bodies and in some larger repositories development of 'internal ethics and governance oversight frameworks including guidelines and policies' (Chalmers et al 2016). These multi-layered and often fragmented approaches to governance cause significant challenges for collaborative research endeavours. Although harmonization has been discussed widely in the biobanking literature, with some suggestion that we may have moved beyond it, to focus on sustainability (Chalmers et al, 2016) there is still a need for the interrogation of key concepts in harmonization in order to gain clarity on whether and how it might be a means of facilitating global research cooperation in ethically justifiable ways.

Some of these operational aspects are and should be standardized, for example variant interpretation; data cataloguing need to be done in standard ways, or information about how

[14] UK Biobank COVID-19 Antibody Study https://www.gov.uk/government/publications/uk-biobank-covid-19-antibody-study-final-results/uk-biobank-covid-19-antibody-study-final-results

they have been processed provided, in order that sharing and aggregation can take place. Standards for describing data and findings are necessary to improve data interoperability and therefore increase utility and sustainability of the data and the biobank(s) and there are ongoing international projects doing this work (GA4GH, P3G, BBMRI-ERIC). However, design and ongoing governance of biobanks may need to be adapted depending on contexts, rather than applying a single standard, and is therefore potentially a subject for harmonization efforts. For example, these elements identified for biobank sustainability by Chalmers et al 2016: consent requirements; ongoing connection with participants; procedures for closure; responding to rapidly changing technology; and funding sustainability.

3.9 Consistency and Harmonization

Consistency is seen as centrally important to both moral theory and lived experience. Without consistency it is difficult to imagine clarity or harmony for ethics and governance of biobank research, or for anti-doping programmes and potential secondary research use of that data.

The insistence on consistency in combination with the view of contradiction as incoherence in theory, and unfairness or inequality in practice, informs much of what is considered worthwhile in moral theory and the object of consistency here is governance and the norms that underpin it. In the world, complex international research programmes are rarely so straightforward as to contain no inconsistencies. This may particularly be the case where multiple organisations, cultures and countries are involved. A neat theory may need to become messy in order to fit the world (Hamalainen, 2020). Consistent theory does not mean a mono-theoretical approach, because it is possible to consistently allow for equally important but different values within a bounded system. Boundaries are needed to delineate what is and is not within the remit of the governance or system but also to establish the limits of difference while remaining viable. Multiple theoretical standpoints may coexist so long as they are internally consistent and able to accommodate others, as opposed to simply gathering support for their own approach. This is important for the core idea of harmonization to accommodate and value multiple voices and complex, potentially conflicting needs that exist in operating across a range of geographies, cultures and resource levels.

A broader pluralistic take on ethics may be better able to respond to the complexity and fluidity of lived morality and therefore be more suited to multicultural settings than a single

set of principles or framework. Plurality is of value in attempts to harmonize and coordinate differing approaches, however it does not resolve the issue of consistency in the way in which Hamalainen (2020) describes it: as a flaw that needs to removed or corrected. This matters in consideration of harmonization because it speaks to the challenges of valuing multiple viewpoints and developing harmonized systems or approaches without losing the value and character of the parts that are harmonized. To do otherwise is simply to standardise; to fix inconsistencies and differences with the goal to generate conformity. An exclusive focus on conforming or standardizing would remove the potential for inclusivity (of multiple viewpoints) and nuance that working towards harmony allows for. It may also increase the potential for dominant parties to overrule others in a way that deliberative, reflexive process that aim at harmonize governance, should not because they have listening and inclusion of difference embedded within them. One practical means of facilitating this is to engage specialist facilitators to support discussion and to develop clear aims (revisable as part of the process) with stakeholders prior to beginning.

Complexity and conflict are not simply to be dismissed but may be the precise spaces in which parties can move to a deeper understanding and therefore achieve harmonization in a meaningful way, once there is agreement about what that entails. Agreeing on shared goals and aims does not necessarily require agreement on the detail of how they are achieved. Nevertheless, it is important to note that it is not an argument for a purely consequential justification. As Hamalainen points out, one value in following different paths at the same time without enforcing an overall structure is that different things may be found out. It is possible to work towards a shared goal (ethical research uses of biobank data for example), whilst remaining open to differences in method. (Hamalainen, 2020).

Consistency is demanded of the account of a theory or state, and of the moral content of that account, therefore inconsistencies are faults; to be fixed. The pejorative description of inconsistency and the demand to fix it imbues consistency with its own weight as opposed to the claims of neutrality for harmonization (Boodman, 1991). It is, however, possible to require consistency in a theory or approach, while equally valuing a plurality of values. As Hamaleinen remarks ‘the different considerations can be harmonized so that they can offer a non-contradictory normative account of our moral lives’ (Hamalainen, 2020: 451). While this quote refers to moral theory, it is usefully applied to the harmonization of practical ethics such as the ethical governance and oversight of international research. That said, seeking to create consistency can deflect consideration of complexities and difference of lived morality

and attempts to make the messy neat may miss the value of differences, for example as opportunities to learn how to do something differently or to critically examine the ways in which a system is set up.

Points of difference and potential resistance can offer opportunities for critical reflection that may not occur in a homogenous environment. In developing ethical governance for research, reflection should be followed by actions where they have been identified. This may be an obvious point to state, however it is not uncommon for stakeholders to make recommendations that do not get translated into actions. This can occur for a number of reasons including lack of commitment from target organisations (e.g., WADA, ADOs, sporting bodies, research councils), or practical issues such as funding, but highlights the importance of working with organisations to understand their needs and level of ethical comprehension in order to develop implementable measures and to build their capacity for ethical reflection beyond the mere application of rules. Reflection and iterative development are at the heart of responsive governance and are also key elements in facilitating harmonization because of the need to actively hear a range of voices and to form coherent systems that are effective in the contexts and for the populations that they aim to serve.

Whether a global network such as GA4GH or WADA, or a smaller scale framework, harmonizing across multiple and different contexts is inherently complex. Greater input from social science and bioethics into large scale systems is needed in order to help identify context-specific challenges and potential solutions. These broad disciplines may provide expertise in drawing out complex needs and supporting stakeholders with developing governance through ethical reflection alongside pragmatic consideration of available resources, ethically justifiable prioritization and capacity for implementing recommendations. This should be managed with the explicit aims of supporting knowledge creation and increasing awareness and comprehension of the power dynamics and structural inequalities that can make the principles on a page appear simple but the real world difficult to capture.

Acknowledging that difference is unavoidable in global research governance as a means to improve - greater understanding and inclusion of lived morality in theory- bridging the gaps. However, this is not a critique of philosophical methods but a cursory exploration of how the ways in which thinking about the ethical dimensions of biobank governance and translation from theory to practice (and vice versa). This acknowledgement can be unpacked in ways

that are useful to the consideration and construction of robust harmonization of ethics in the research context.

In thinking about consistency and plurality the well-rehearsed question of whether there are any exceptionless rules arises. An obvious response is that even killing may be justified in certain circumstances. Therefore, an absolutist approach cannot be defended in practical terms (even if it could be on theoretical ones). Nevertheless, the equal weighting of one moral system or belief against another on the basis of some permissive relativism is untenable as there are shared values between and within societies that do carry more weight than others, such as the prohibition of killing except in certain limited circumstances. The application and interpretation may differ and there may be greater value differences such those around individual consent or who is authorized to make decisions about a person's treatment or research. Collaborative international research work requires some shared norms, or a shared goal and norms that meet or at least do not contravene, agreed central parameters or boundaries that may be sufficient for cooperation but have some inconsistencies. An example of a relevant shared goal is that of maximizing the utility of data for research through sharing or providing access. This might be achieved in a range of ways, such as use of TREs, cloud services or through secure sharing methods and may include ethical oversight from a REC or similar.

Differing levels of access to resources, geography, language and cultures may impact what method is chosen, as well as the type of research being carried out. However the ethical use of data is practically achieved, some shared norms that are relevant include respect for autonomy, privacy and the need to demonstrate trustworthiness on the part of the researchers and data stewards or custodians (organisations that collect, store and manage access to data). Even where broadly shared, there may some small differences in conceptions or applications, for example the demonstration of trustworthiness may not look the same to all people in all contexts at all times. For collaboration to work there does not need to be absolute agreement so long as there is sufficient shared value, understanding and accommodation of differences within agreed boundaries. This can be as relatively simple as recognition or a more involved harmonization of elements.

Paying attention to inconsistency is not quite the same as acknowledging differences because differing theories or values may still be consistent in themselves. Internal consistency is fundamental for viable theory and to practical systems. Harmonization can be thought of as

moving towards common goals that can be reached in different ways or from different startpoints that are consistent in themselves but inconsistent with each other, allowing for a multiplicity of ways to reach the agreed endpoint, but noting that plurality is bounded and therefore there are constraints on what is allowed within a harmonizing system. An example from anti-doping would be the ways in which norms between sporting organisations and athletes may differ despite the fact that they adhere to general rules about what behaviours are allowed (Loland 2002).

Importantly, Hamalainen is not suggesting that attention be paid to inconsistency as a means to improve theory, but that moral inconsistencies 'often contain important insights about our moral situation' (202: 454). Moral thinking and the actions that follow are not static, but in a constant state of adaptation ; responding to observations, occurrences and situations encountered. Much of this occurs without conscious thought and is therefore easy to overlook, or to parcel in with emotional reaction, but the difference matters. Interpretive responses and shifts, even if subtle or potentially unacknowledged by the agent, affect the way that an agent moves through the world and therefore how they affect others. At the macro level of a large-scale research programme, it would likely be impractical and counterproductive to allow for all of these responses to be written in to frameworks. Yet understanding complexity and fluidity at both the macro and individual level can help us to understand how frameworks are perceived and may be put into practice. These ideas will inform our ability to accommodate difference and inconsistency without being so loose as to lose validity and conversely not enforcing similarity or consistency for its own sake.

Hamalainen (2020) asks what the price is of forcing a consistent solution to a problem- we ought to assess the role and moral value of consistency in a given case- it cannot be assumed to always be the ethically appropriate goal. Differing responses to a challenge can still be fair and in the case of developing research governance, should be ethically as well as legally defensible. Strong harmonization and an overarching narrative that can be usefully and appropriately applied in multiple contexts may suffice. We might introduce more subtlety and flexibility into existing harmonized systems by allowing for non-standardization and accepting that shared goals need not require identical means of achieving them. There do need to be parameters for what is acceptable within such a system, not everything can be allowed without risking the sorts of ends-based justifications that directly contravene research

ethics core norms. Embedding 'practical intelligence'[15] and space for disagreement in complex systems that in fact often are not one system, but may be closer to a mosaic of smaller systems 'harmonized' under one umbrella. An example of this type is the structure of doping control in sport, where national and international anti-doping organizations (ADOs) govern their own jurisdictions under the central guidance of WADA with explicit harmonization of regulation, sanctions and testing processes for example (See Chapter 5 and 6 for further detail). In research the GA4GH workstreams aim to develop frameworks and tools that can be applied by local systems, sensitive to context and based on shared acceptance of core values (GA4GH, 2014; WADA, 2021). Their documents and some processual information are made publicly available and products can be used without license.

Bespoke harmonization approaches will also benefit from this increasing integrity and potentially increased sustainability (if we accept that 'buy in from stakeholders is key to biobank sustainability) and thereby allowing for context and lived experience in a range of ways, including the involvement of participants and data contributors such as those athletes with data in ADAMS in the design of systems (See Chapter 6). These should be done as appropriate, and based in sound ethical reasoning i.e., not just the expression of power or preference (Sheehan et al, 2019).

Thus far, skeptics might accept that morality can function without being completely consistent and that lived morality is in part based on experiences that inform our worldview two sentences, however they might argue that where possible, moral theory is better if consistent and coherent; the lack of consistency being tolerated but ideally removed or lessened. Hamalainen argues *a fortiori* that inconsistencies are 'an irreducible trait of any functioning morality' (2020:461) They serve a useful and important function: positive adaptability. Not all inconsistencies are positive, some may be mistakes, but some afford opportunity for improvement or progress. This may be particularly true at points of conflict or step changes in existing ways of practice, for example when dominant paradigms lose their power or new ways gain ground. It is not wrong to seek the ideal so long as it is not at the expense of lived experience. Striving for clarity and coherence is not mutually exclusive with accepting and valuing complexity and difference. Such actions are a part of the process rather

[15] Practical intelligence, commonly referred to as 'common sense' is the 'ability to adapt to, shape, and select everyday environments'. It includes the procedural knowledge that is usually not formally taught and may be in part subconscious, but is an important tool for thriving in a cultural world (Sternberg et al, 200). Practical intelligence exists in all cultures but the components of it may look somewhat different between cultures.

than ends in themselves and can co-exist without being contradictory and this is explored further below.

Adhering to rules or principles in the face of changing circumstances can lead to conflict and to ineffective frameworks that do not capture/provide that which is needed and potentially may even cause more harm than good. E.g. individuals and groups react in different ways to similar information or situations, largely informed by their culture, socialisation and the norms of the sphere in which they are currently operating e.g. biomedical research. Relationships to persons, power and facts are not static, but are negotiated as things shift and with time. This requires space for flexibility but with boundaries- it is not a suggestion of free for all. Harmonization, as opposed to standardisation, may provide such space and flex, respecting the need for plurality and acknowledgement of the importance of change and difference, without recourse to relativism. Lack of cast-iron rules may mean that transgressions are harder to identify or to sanction, yet they also offer opportunities for development. By not just acknowledging but valuing difference and inconsistency space may be created for positive change.

In the dominant moral and political schemes of the global North (US/Aus-NZ/Can/UK/EU) order and certainty are highly prized. Structure and operationality achieved through shared understanding and implementing standards where needed ie technical and logistical, are vital to the success of any complex large scale endeavor. However, attempting to capture morality and create applied ethical rules in the same ways seems to be a mistake. A standard, rather than harmonized, approach to ethics across global biobank research would likely impose a Global North agenda and ways of knowing onto all settings due to where frameworks and funding tend to originate and the requirements of that funding to evidence outputs in closely specified ways. This domination of global research by a few rich nations is a well long-acknowledged issue, subject of a growing and interdisciplinary literature (See Varmus & Satcher, 1997; Bull, 2015; Jao et al, 2015; Pratt et al, 2018) that is particularly relevant to biobanking due to the need for large amounts and diverse data and to the impact of resource-inequality on the ability to benefit from the research that data enables (Jao et al, 2015). A deliberative, harmonized approach to the development of ethical governance may help to mitigate by allowing for a range of actors to a) contribute to deciding direction and b) apply responsive governance approaches in context-specific ways. Practical ethical guidance and governance is much needed and will in some ways look similar to the operational standards

but the root must be openness and valuing difference in complexity, not attempting to reduce complexity to one 'note'.

The case to which I apply this thinking about harmonization is an unusual one: potential biomedical research uses of data arising from anti-doping activity in elite sports. This case is significant because it sits at the intersection of medical and non-medical bio research. Athletes must provide certain data and biosamples in order to compete therefore there are questions to be asked about the validity of the primary consent and following that, any consent to research uses of those samples and data. The ADAMS database (biobank) is global in reach and the owner WADA is a global organisation with significant and far-reaching power over many aspects of data contributor lives. It is also one that expressly claims to take a harmonized approach to the governance and operational conduct of anti-doping at all levels of sport. This combination of factors creates a uniquely challenging context and I take this opportunity to examine concepts by applying them to ADAMS, noting that research access has not yet been approved. This is, therefore, an opportunity to interrogate how current approaches to harmonization in research and learning from existing WADA systems, might be adapted or novel means introduced in order to facilitate the ethical use of athlete data for research purposes beyond anti-doping. As part of this interrogation of harmonization and associated concepts, next we consider the relationship between pluralism and harmonization (as it applies to the development of ethical research governance and the ADAMS case).

3.10 Pluralism and Harmonization

A pluralistic approach needs to captures moral diversity without being so broad as to be of no practical use. This may require acceptance that complete agreement is unlikely and that consensus building can be valuable but can also exacerbate or create power imbalances. Where that is the case the 'end product' may be closer to an adjusted dominant paradigm than a meaningfully deliberated choice. If so, then we might accept it as progress and use the successive iterations of governance to effect smaller but sustainable gains in choice-making and continue the move towards deliberative governance.

Turner 2003 (in Durante 2008) observes that 'customary normalities' are often seen as less sophisticated and are therefore less valued, than philosophical reasoning. There has been wariness of pluralism in particular due to the perceived 'slippery slope' to relativism. It is not necessarily the case that pluralistic outlook is at risk of relativism, as a key difference is in

how the two approaches consider what is right and wrong, for example a relativist might claim that there is no 'wrong' way to do x because all viewpoints are equal and we cannot establish any one as being more valid than another. This is not the case for pluralism, which is bounded, recognizing the value of a range of norms but not seeking to establish the 'truth'. There are good and bad, right and wrong moral actions, and all moral decisions require justification. In this way, pluralism can be described as being more concerned with how a range of values in view relate and potentially inform each other and what counts as permissible and/or good in a society.

In 'Reconciling pluralism with the normative structure of bioethics' Durante (2008:37) calls for the bringing together of social science and bioethics in order to gain deeper and different understandings of the cultural, moral and contextual diversity that informs thinking and that ethics and governance for population research needs to better account for. In a situation where there are very different moral views and cultural identities attempting to construct a shared framework, it is important to understand and accept that agreements can be reached in different ways. For example, two parties might not agree about a specific consent model on moral grounds but they may reach a compromise or working agreement because it is politically or economically expedient.

One way of reaching consensus that I will discuss only briefly, is contractarian negotiation based on rational discussion and bargaining, after Rawls' 'reasonable pluralism': moral theory based on a negotiated moral order that remains flexible enough to allow some change and can be re-negotiated in the future. However, this approach has built-in flaws in that it requires a shared (Western) concept of rationality and of human nature (Durante, 2008:38).

Adapting clinical pragmatism seems a potentially viable approach: a middle ground between principle-based universalism and particularism that is inclusive of differing views and 'context respecting' but with boundaries that contain the central aims and values. However this kind of pragmatist approach does not engage with the beliefs that inform personal ethics, but instead relies upon a particular conception of the rational and on scientific methods. This approach does not suggest metaphysical discussions that aim to resolve a question, but that beliefs need to be explicitly acknowledged and understood in relation to a particular perspective. This may be especially the case where there is seemingly intractable disagreement on a position or for example, governance proposal. It also points to the value of

holding space for differences and not having unanimity or consensus as the only possible end goal.

Ignoring beliefs in favour of 'entirely rational' dialogue diminishes the capacity of the process to deal with moral diversity. Identifying and acknowledging (the validity of) difference before attempting to work towards agreement mitigates against the default or existing approach being tinkered with at the edges and potentially used to impose standardisation. This approach creates space for movement towards something more like harmony. Once again, there are contexts in which standardisation is needed e.g., interoperability for laboratory procedures, but ethics and governance of human derived research requires a more complex approach that is capable of capturing nuance and remaining flexible. It is not a failing of a governance development process to establish that there is shared understanding of what parties do not agree upon. One can imagine a start point without shared understanding even of the basis for disagreement. Relying on consensus can be divisive and as previously stated, exacerbate existing inequalities whilst giving an impression of agreement that resolves them. If consensus is not the only viable goal or method of progressing then we must consider the alternative: working in diverse and potentially conflicting beliefs towards a shared aim.

Stout (2001) theorised that it is possible to accept 'moral diversity' without abandoning the idea of universal morals or truth. This seems paradoxical at first but the acceptance refers to beliefs held about a moral law or principle rather than the law itself. This applies whether or not the law is 'correct' because, according to Stout, it is socialization, and culturally determined expression thereof, that informs the ways in which an agent will judge and therefore behave in a given situation, rather than the facts of the situation alone. Differentiating justification from truth means that it is possible to hold an incorrect belief and still be justified in that belief. The possibility of holding differing beliefs while being able to move towards a shared end goal is explored further below.

Durante holds that 'Two epistemic contexts may differ to the extent that they are able to justify conflicting propositions; it does not necessarily follow that they will never be able to justify the same proposition' (2008:43). This way of thinking is key to harmonization of ethics and governance in multi-jurisdictional research because it identifies the possibility of parties holding differing views on a range of things, but still being able to agree. Moreover, that justification does not have to have the same basis for each party in an agreement or

harmonized system. Under this conception it is entirely reasonable to arrive at a place from differing routes. Allowing capacity for this to happen is vital and in fact may require more action than simply allowing, for example proactive coordination and facilitation of discussions. This approach needs background work to establish rules of engagement so that process is as inclusive and productive as possible, retaining flexibility and being open to difference and, importantly, to failure. It should be noted that this will likely require a shift in mindset, or 'culture change' from commissioners and funders to allow for significant changes later in a process than might 'normally' be expected. We might reasonably anticipate resistance to such a request on the grounds of increased time, expense and the explicit acknowledgement of either failure or significant changes as a possibility. Meaningful attempts to change thinking and translate into actions should draw upon a combination of information, ethical governance and practical judgement and the reasoning for combining these aspects is explored briefly below.

O'Neill (2018) critiques principles as being either too broad as to have meaning, or too narrow/rigid to allow the interpretation needed for them to be practical. This creates difficulty in moving from principles 'on paper' to action in the real world. In order to be action-guiding, which for O'Neill (should be a central aim, principles must be coupled with practical judgement. It is this practical judgement, described by O'Neill and drawn from Kant, that provides the contextual, situation-specific expertise in a principle-based system of ethical governance and can illuminate seemingly quite diverse circumstances or cases using the same sets of rules or principles. This symbiotic relationship between rules and judgement and action is fundamental to the effective and ethical conduct of population biobank research. This may sound like a simple solution- simply apply practical reasoning alongside practical principles, however, determining who and what informs and carries out these activities is far from simple, even less so when factoring in normative differences and language barriers. Some of the complexity has been drawn out in this chapter but further work is needed to discover some effective ways of moving from principles to action that can be harmonized. This should be accompanied by ongoing evaluation of how the resulting actions can inform further iterations of the principles. There is relevant work from political science and law regarding reflexive governance and deliberative methods, as well as from public involvement and engagement, however that is not specific to developing processes to be harmonized[16]. The development of governance for research uses of the WADA athlete data, with specific

[16] Examples include Dryzek & Pickering, 2017; Elstub et al, 2021; Laurie, 2017.

challenges inherent to the doping control context (See Chapter 5 and 6 for detailed discussion) and where core activity is already centred on harmonization, would provide a particularly interesting setting in its own right, with some features shared with broader biobanking. The following section concludes this chapter by summarizing and considering how to apply key points to the context of WADA-ADAMS.

3.11 Conclusion

Understandably, there has been prioritization of operational over conceptual work regarding harmonization, in order to get international population research 'up and running' . The acceleration of technological ability and capacity in combination with a significant decrease in cost and time continues to drive rapid research development and expansion. External forces such as the global pandemic beginning in 2020 have further accelerated international population scale research efforts. At a time when sustainability, diversity and global access to benefits from research need to be at the forefront of the ethics agenda it seems appropriate to re-interrogate central concepts to consider how appropriate they still are and how they might be applied in the future.

Harmonizing ethical governance for research is a long term and complex project. It seems sensible that where systems share an ideological or intellectual basis they might be able to achieve mutual recognition and a 'harmonization' framework may not need to do much more than enable that for some aspects of governance. The example of GA4GH's Ethics Review Recognition Policy based on the Framework for Responsible Sharing of Genomic and Health Related Data (the Framework) illustrates this approach: 'Ethics reviews undertaken in light of this Policy would reflect sufficiently similar procedural approaches to the assessment of the ethical acceptability such that duplicative ethics reviews can be reduced through recognition of the review of another ethics jurisdiction' (GA4GH, 2014).

In some instances, global research requires sharing of information and resources with very different systems and this may present greater challenges to attempts at harmonization. A start point seems to be agreement of a common (research) goal with corresponding identification of commonalities in existing ethics and governance approaches. It is unlikely that there will be no points in common at all. It remains important to recognise and value difference as well as seek similarity, in order to avoid a default move towards standardization.

GA4GH and others have been considering the challenges of harmonization in the ethics and governance of population biobanking and genomic research for many years. There is unlikely

to be one ‘solution’, but it is important for a sustainable and more just future for collaborative biobank research that we continue to work towards ethical governance frameworks that allow local and temporal reflexivity and sensitivity with sufficient shared normative bases to facilitate shared ethical governance in global research. Working within practical bounds and prioritising those aspects likely to be taken up by relevant parties does not exclude aiming for more.

The main aim of this chapter was to conduct a retrospective interrogation of harmonization concepts to justify their use and relevance and inform consideration of the utility and practical challenges involved in working towards harmonizing ethics and governance for biobank research. Not insisting on a standardized approach with identical application may mean that transgressions are harder to identify or to sanction, however it also means that there is room for ongoing development and inclusion. By acknowledging difference and inconsistency, room may be created to effect positive changes to more rapidly and for small and/or marginalized group contributions, or valid resistance to the status quo, be heard. A risk of such an approach is that negative effects may also occur more easily, but through monitoring and iterative development of ‘good governance’ determined by consulting best practices in other settings as well as through engagement with stakeholders, risks can be minimised and mitigated where necessary.

The case to which we apply this thinking about harmonization is an unusual one: potential biomedical research uses of data arising from anti-doping activity in elite sports. This case is significant because it sits at the intersection of medical and non-medical population research. Athletes must provide certain data and bio-samples in order to compete in high level sports and therefore there are questions to be asked about the validity of the primary consent and following that, any consent to research uses of those samples and data, a topic that is explored further in Chapter 6. The ADAMS database (biobank) is global in reach and the owning organisation (WADA) is a global one that expressly claims to take a harmonized approach to the governance and operational conduct of anti-doping at all levels of sport. This combination of factors creates a uniquely challenging context, and therefore opportunity, (explored further in Chapter 6) to examine harmonization concepts by applying them to ADAMS, noting that research uses of ADAMS outside of anti-doping have not yet been approved and therefore now is the time to interrogate how current governance and methods of development of governance might be adapted or novel means introduced, in order to facilitate the ethical use of athlete data for biomedical research purposes. Harmonization

efforts are no magic bullet that can prevent or solve existing power imbalances or resource disparity, however the deliberative processes involved should create space for progress within research communities.

At the current time there is an opportunity for WADA to be proactive in gaining clarity regarding specific difficulties and identify potential 'wicked problems' that may need to be worked through before commencing policy and systems development for wider research access to ADAMS.

Harmonization is motivated by improving practices, ease of use and access but also to supplement law/ provide systems for governance where there is a gap in the regulation or lack of clarity, by creating systems that have been agreed by all or a majority of parties who will use them. For Townend (2018) treating research and commercial uses in the same way is problematic and there should be a separate consideration of research that involves examination of the 'conceptual underpinning to emerge'. Even if there is no 'perfect harmony', it remains an admirable goal to work towards and there are still practical and social benefits to engaging with the ideas. This thesis aims to contribute to that much needed and valuable undertaking. The following chapter provides an overview of the development and governance of anti-doping in order to locate the ADAMS biobank in the world of sport and providing background for Chapter 6's exploration of ethical challenges to potential research uses of ADAMS data that arise in that context.

4 Consent

This chapter provides an overview of consent as it applies in large scale genomic biobank research and with specific application to the potential research uses of the WADA-ADAMS database. The considerations surrounding consent raised in this chapter should contribute to the understanding of ethical and regulatory practices by considering how to meet the challenges of innovating ethical governance in the context of biobank and data research. The careful consideration of underlying norms that inform how consent and other aspects of ethical research governance are conceptualized will support the development of constructive relationships with data contributors. It also helps to illuminate ways in which data can be shared in a manner that is both ethical and supportive of the research aims. Appropriate consent is one of a suite of measures key to developing and sustaining the success of collaborative biobank research and will be central to recommendations made later in this thesis for the potential future use of ADAMS data (See Chapter 8: Conclusion). The chapter firstly discusses the traditional account of informed consent, rooted in the clinic, and possible alternative consent models applicable to biobank research, listed below. Many ethical issues arise from the use of biobanking, of which consent is a critical and highly debated one. Other issues include privacy, confidentiality, benefit sharing and respect for autonomy. This chapter begins with an outline of the biobanking context, a discussion of the ethical role of consent in research then the traditional model of written informed consent for the acquisition, storage, sharing and analysis of genetic data and articulates the challenges to it from new research practices such as multi-omics biobanking. Models of consent are evaluated for their justifiability and fit with regard to population scale and multi-national biobank research. The specific problems of research conducted at scale and over long periods, often with highly heterogenous cohorts including patients and well participants include deciding whether consent is an appropriate basis for all research interactions and, where so, on the best consent model for that research context.

The focus for this discussion of consent to research is on well participants rather than patient cohorts, and on those adults who have capacity to provide valid consent to research using tissues and data originating from them. This is followed by critical consideration of five other consent models currently in use: blanket consent, broad consent, meta consent, dynamic

consent and waived consent. It is argued that these models or conceptions of consent must be considered in the context of the complexities of international regulation including legislation and other non-binding instruments collectively referred to as 'soft law' [17]. The complexities of international regulation and biobanking governance, as well as balancing the interests of participants and research, are challenging in a field where research and technical capability moves considerably faster than ethics guidance and law.

Consent is the most broad and significant overarching concept that ties together ethical concerns such as the respect for individual autonomy[18] and it is central to consideration of the ethics of biobank research practices (Sheehan et al, 2019; Holm & Ploug, 2017). Moreover, researchers and clinicians may fail to understand the different models of consent and their ethical nuances, specific informed consent remaining the 'gold standard' in many contexts. So that subjects, participants and patients offer their valid consent, researchers must consider which model of consent they will operate with and have a clear justification for it.

Population scale research and particularly open or hypothesis producing research presents challenges to the traditional clinical model of consent. It is a setting that is distinctly not one-to-one, that may take place without personal interaction, and therefore requires a reconsideration of what has traditionally been deemed the most appropriate model to facilitate consent to research: specific informed consent. In this chapter, I critically explore the main consent models and consider how appropriate they are for population-scale international biobank research.

Current understanding of consent is widely acknowledged to have arisen from critical attention to the governance of clinical research, originating from the Nuremberg Trial principles (Nuremberg Code) and modified by the various declarations of the World Medical Association with the aim of protecting participants in single research projects in a single place (WMA, 2013; 2016). Two fundamental conceptual aspects of the traditional model of consent are voluntariness and informedness. Voluntariness refers to decisions made by potential participants free from coercion or undue influence. Informedness requires the decision-maker to have reasonably sufficient information to consent or refuse based on that information. Despite the widespread agreement about the general dimensions of the consent (absence of coercion or undue influence; expected benefits, expected risks and safeguards;

[17] See Chapter 2 for an account of the regulatory landscape surrounding biobank research.
[18] A brief overview of relevant models of autonomy is offered on p50-51

maintenance of privacy, anonymity and confidentiality; provision of verbal or written information regarding the project aims; right to withdraw without prejudice; and so on) it is nevertheless often a matter of interpretation as to what constitutes a reasonable level of "informedness", or when secondary or tertiary requests to participate are considered robust or coercive. Researchers are required to carefully think through the inherent complexities of the research and the specific competence or capacity of participants to understand a particular project or intervention. The older phrase "full and free informed consent" has been exposed as being impossible to fulfil: In principle, no one can know all of the possible consequences of any particular research project and especially so for inductive approaches where the data may be interrogated relatively broadly (but within approved parameters) in order to uncover patterns and associations that would otherwise not be seen. Very rare conditions or other characteristics with small populations rely upon very large-scale datasets in order to obtain reliability in the effects. What counts as reasonably sufficient and appropriate information is often a matter of interpretation, modulating between the inherent complexities of the research, and the competence of the participant.

In biobank ethics, informedness is a particular concern due to the highly complex nature of the research and the innovative methods involved. Many research projects are constituted by highly specialized teams, the members of which are themselves not expert in all aspects of the technology comprising the research, so it is difficult to see how the public can fully grasp such information to a level required by informed consent. Currently, there is no consensus on how much and what type of information is needed for consent to be informed. There is an identified 'information gap' between data curators and technicians, researchers and participants (Caulfield & Murdoch, 2017; Sheehan et al, 2019). There may be additional cause for concern if only a small number of people understand the systems and risks, and they are not the people explaining participation to donors. Fast-moving, highly complex, technology adds to the complexity of the ethical aspects of consent and governance more broadly. This can lead to reactive legislation, or defaulting to the most proscriptive applicable regulation where multiple jurisdictions apply, rather than choosing an approach that best fits the context (Sheehan et, 2019). Under these conditions – a version of the precautionary principle may be applied that is disproportionate – ie more prohibitive than is strictly necessary for protecting participant interest (Allen & McNamara, 2011; Manson & O'Neill, 2007).

Standards of consent based on 'ideal' situations that in practice may seem impossible to meet can lead to a lack of adherence and even a de-prioritisation of good quality consent with recourse to the 'tick box' ritualised version. Lowering of standards, or acceptance of significant differences in the application of standards depending on difficulty may fail to solve the challenges of informed consent in population research. Manson & O'Neill (2007) note the need for feasible standards for all parties involved in consent processes, be it seeking, giving or refusing of consent. Standards must include checking of understanding as well as communicating information: Disclosure is not sufficient whether consent is to governance or directly to research purposes. The epistemic quality of interactions in the consent process impacts a person's ability to consent. This may be more pronounced in consent for clinical research and treatment due to the higher risks and more obvious power imbalances between patient and healthcare practitioner, but it also figures in non-clinical research.

Some groups and individuals might be considered to be more vulnerable or less empowered than others with regard to research participation and, for athletes, consenting or refusing use and access to their doping control data, due to their status in society and historical experience with research and medicine, for example, racially and/or economically-marginal populations including those with colonised histories. Whilst feasibility is important for achieving consent, increased specificity does not necessarily increase quality. The basis for supposing that it would is a conflation of increasing choice with increasing autonomy protection. 'That some act is chosen is, after all, neither necessary nor sufficient to justify doing it' (Manson & O'Neill, 2017: 185). The balancing of autonomy as one among several kinds of interests does not in itself explain the need for consent. There may be cases where consent is not required and therefore it is necessary to consider in what circumstances consent to research may or may not be needed and on what grounds the decision is justified. A common way to assess the need for consent, and what kind of consent is needed, is to take a risk-based approach. Where there is a high level of risk, such as in invasive clinical trials, it seems reasonable to require strict specific informed consent (including information on all known risks and their severity, likelihood). The other end of the spectrum is 'minimal risk' data-based research which can be conceived as either low likelihood for some harms or that the potential harms are insignificant, or some combination of those. The role of consent is broadly the same regardless of model or risk level and requires certain conditions to be met. Those conditions and the role of consent are discussed below.

The role of consent is to permit actions that would otherwise breach existing known rights held by the person from whom consent is sought, for example, the right to bodily integrity; to private and family life. Informed consent is 'used where an agent has reason to permit derogation from a significant obligation or expectation that would otherwise be breached' (Manson & O'Neill, 2007:188). Rather than applying particular consent models per type of information eg medical, administrative, especially given how poorly defined the boundaries between the types are and how they change over time[19], it may be better to base the choice of consent on the level of risk of harms, or wronging. Harming and wronging are two closely related concepts that are subjects of an extensive interdisciplinary literature that includes philosophy, law and psychology. In order apply them in considering consent and other ethical challenges to ethical use of biobank data and samples, we briefly outline consequentialist and strict moral accounts of harm and wrong, relating them to research. Consequentialist accounts of harm rely on whether the person's interests or well-being have been significantly worsened in some way.

Wronging can be considered in terms of consequences but that will not satisfactorily characterise the features of wronging as opposed to harming. A person may be physically or otherwise harmed without necessarily suffering a 'wrong'. Kumar (2003) gives the example of a person who is injured by an animal trap while hiking- if the trap is left by accident then they are harmed but we would not necessarily claim that they were wronged. However, if the trap has been put there with the intent to stop people from crossing that land, for example, then it seems they have been both harmed and wronged. Wronging therefore has a moral component that is distinct from an outcomes-based account of harms, and intention matters, while noting that it remains possible to harm or wrong someone unintentionally. It is also possible to wrong someone without them being meaningfully worse off as a result. A well-used example of this is the transfusing of blood for someone who would refuse on religious grounds- their life has been saved and therefore at a fundamental level, their interests have been supported, however they have suffered a wrong due to the transgressing of their sincerely-held beliefs. At the boundaries, harm meets wrong and in particular for the kinds of wrongs relevant to biobank research such as those suffered by e.g. Indigenous peoples through retention of data or samples without express permission (See p145 for the Havasupai example).

[19] ADAMS is a particular example of the blurring of boundaries between data types due to the sensitive health-related and geographic data it contains- collected for anti-doping and not medical or research purposes, but potentially used for research including biomedical. See Chapter 6 for further discussion of ADAMS.

If we require there to be some type of objective harm, rather than the perception of harm alone being sufficient for a valid claim, we can consider harms to a person's autonomy in a similar way, for example through unjustified choice restriction, or withholding pertinent information. Following Feinberg and Kumar, these wrong the agent and can also lead to harmful consequences e.g., agreeing to uses of data or samples that do not reflect their personal morality, or interventions that are not appropriate.

Separating the moral wrongs (and harms) from the harms that arise as result of the choice is helpful (Maclean, 2014) to better understand the elements of wronging and harming and also to illustrate that the consequentialist approach alone is not sufficient to describe the range of experiences that we intuitively understand as wronging, whether there are tangible consequences or not (Kumar, 2003; Feinberg, 1990). A further way to conceptualise the 'harmless wrongdoing' (Feinberg, 1990) discussed here is offered by Judith Thomson, who differentiate harms from distress in the Harm thesis: 'we have claims against others that they not cause us harm' and the Distress thesis: We have claims against others that they not cause us 'non-belief-mediated distress' (1990: 250). For Thomson there are feelings 'we just have' e.g., pain, that are 'non-belief-mediated' and those that arise because of particular beliefs e.g. moral indignation; anger. This distinction does not exclude being morally wronged but rather that moral indignation by itself is not sufficient for wronging or harming. Thomson uses distress to describe aspects of what Feinberg and Kumar have called harmless wrongs. These ways of conceptualising harm and wrong and comparing the two, are of particular interest in comprehending the range of experiences and viewpoints relevant in reflexive working towards harmonization of ethical governance for global biobank research and we can use them to further understand specific challenges- epistemic inequality[20], for example.

The information type may inform the perception of risk and sometimes the actual risk of harm or wronging arising from consent interactions, but it is not the sole factor. Other relevant aspects include the research purposes (as known) and the context in which the participation or contribution takes place. Where consent is not valid i.e. it does not meet conditions of informedness, comprehension and voluntariness, it is not transformative: it does not transform an action that would normally be considered a breach of rights into one which is acceptable. Where consent is transformative, it acts to transfer the moral responsibility for

[20] See p172

the consequences of the action for which consent is being sought, on to the consent seeker (Manson &O'Neill, 2007). Where consent is valid, and therefore transformative, the act itself is not altered and may look the same to an observer, but the ethical weight of it is. One of the key aspects of consent is voluntariness, a much-discussed and contested term: Contested both in terms of definition and the importance that should be placed on voluntariness and its role in the validity of consent (Feinberg, 1973).

Biobank participants are usually not paid for their contributions (they may receive expenses) and therefore the respect for autonomy and the flow of information may be considered to be a form of currency. This does not, however, mean that there is any kind of employment or the associated rights and duties. The idea of freely giving data and samples to research because of altruistic motivations also feeds into the narrative of currency and respect, but caution must be applied. The framing of contribution to research as altruistic can also be used to justify exploitation (Folbre & Goodin, 2004; Jansen, 2009) and to avoid compensating people where it would be appropriate. Altruism and voluntariness are linked: there is no altruistic act without it being voluntary, however, the distinction between inspiration and pressure can be difficult to determine. For example, a contributor who chooses to donate time, data and samples due to the medical condition of a loved one may do so to support the discovery of a cure or treatments. This may be a free choice that is taken with the aim of helping others as well as their loved ones, but it may also be done under the impression that a cure will be found in time. Consent is not voluntary without also being informed and that information understood so that at a minimum there are no significant misunderstandings or omissions.

Consent demands are higher for research than for clinical practice, due to the lack of direct benefit to the research participant compared with the patient in the clinic who should gain from the acts to which they offer consent. There are benefits to participating in research in terms of self-perception and sense of contribution to society that may be harder to measure or describe but nevertheless are valid.

Biobank research requires highly complex technological methods for the combining, analysis, sharing and securing of data. There is often uncertainty about the uses of data stored therein. Research questions are generated from analysis of a range of concerns: for example, combining health or performance-related data with genomic data to discover a variant linked to a disease or condition, or patterns of association of particular variants with, susceptibility to injury. The openness and scale of collaborative biobanking set it apart from the traditional

exploration of explicit hypotheses in a focused study. This highly technologised and open-ended nature generates ethical ambiguities. These include potential harm from malicious or unintended re-identification, the uncertainty of research purpose with implications for consent; and blurring of lines between tissue, data and information, with implications for ownership and access (Thompson & McNamee, 2017; Sheehan et 2019). The complexity of the technical processes involved is a challenge for informed consent. As the complexity of research processes, infrastructures and linkages increase, the ability to comprehend in a way that is supportive of valid consent decisions decreases. This could lead to a decline in participation or a decline in ethical standards where consent is required to be informed. However supplying information as the project continues, and extending communication to require checking of comprehension of complex information may go some way to mitigating these challenges. A shift in the focus of information from research to the structure and governance of the biobank itself will also assist in this aim and may be an ethically superior basis for consent. This will be discussed further on (Section 4.8) and will not be one-size-fits-all as there are known specific challenges and needs for specific populations, this being one of the reasons why a lack of diversity in biobank samples and data banks is problematic.

Lack of population diversity is a known problem in genomic biobank research and the facilitation of appropriate non-written consent processes may be one way to support an increase inclusivity, both of a variety of ethnic groups and socially disadvantaged groups within ethnicities. What constitutes diversity itself is contentious since it is not clear that how constructions of race or ethnicity answer the problems. The value of data derived from specific groups' genomes is such that in the past unethical research practices have taken place, leading to the need for more stringent protection of indigenous and other marginalised groups' rights. Whilst improvement in practices is ethically better for both participants and the continuation of research, we must be alert to 'ethical colonialism' and the uncritical imposition of norms of the more economically and technologically wealthy world onto less well-resourced or powerful communities (Abadie, 2015; Benjamin, 2019; Tindana, 2019). There is often high genetic and cultural diversity within a group designated as a particular ethnicity, requiring sensitive and informed approaches to seeking consent and to collection of samples and data. A potential social benefit of biobank research is a better understanding of

genetic diversity and how it relates to constructions of ethnicity, but this is beyond the scope of this thesis[21].

Setting out clear and achievable consent processes at the outset, having been designed with participant input and retaining flexibility in mind, in conjunction with appropriate ethical oversight and governance should lead to greater adherence to and confidence in consent processes. Where the initial requirements for facilitating research participation are ethically sound and practical, and the ongoing arrangements developed in the same way it should enable participation at very low risk arising from appropriate and well-managed consent. This should mean there will be little room for researchers to deviate from them except by deliberate choice.

More recently there has been a highlighting of consent to a model predicated more on respect for autonomy understood as self-governance. It is often described using the legal term of 'capacity' but refers essentially to the capacity of acting in an informed and self-directed manner consistent with one's goals and aims. The dominant norm for consent in the UK and Europe is written consent, where surrogates are permissible for those who lack capacity. This is not a legal requirement, as verbal consent usually has the same status in law as written form, noting that verbal consent must be recorded and stored (ICO, 2020). Given that the first wave of bioethical research was based on the individual patient-clinician relationship, a key question is– in the light of biobank development - the extent to which this model is fit for purpose in the context of population research. There are some ethical differences between the traditional model and the requirements of research that is reliant on data and samples at scale and lies broadly within a public health focused model. An example of such a difference is the relationship between the person seeking consent and the person who may grant it. In clinical research or therapeutic settings, it is common for the actors to be known to each other or at least have some personal interaction prior to the treatment or research activity. This is not usually the case for population research and therefore the 'human element' of trustworthiness[22] and credibility (which should be noted as being vulnerable to a range of biases and is therefore not suggested as an objective test) is not present. Additionally,

[21] Moves to increase diversity in research datasets and in the reference genome have gathered momentum in the last decade. For example, Genomics England launched its Diverse Data Initiative in 2021, with the aim of reducing health inequalities and improving genomic medicine services and outcomes for patients (Genomics England, 2021). There is an extensive and rapidly growing literature around diversity and genomics biobank research. Examples include Fatumo et al, 2022; Benjamin, 2019; Abadie, 2015

[22] See p42-43 for a brief discussion of trust and trustworthiness

biobank and other forms of research that link and/or make multiple use of datasets may do so over time from one source of consent. This is in contrast to the consent per action model of clinical interaction. Another key difference is the distance between the consent-agent and the potential results or benefits of the research to which they are being asked to consent.

Regardless of the norm for first-person written consent, in a primarily oral culture, or where participants do not write for some other reason, this may be problematic for reasons of trust. A global collaborative group that conducts its research in a variety of contexts outside of medical institutions like hospitals, will operate across a range of cultural norms. Therefore, it must include adaptive strategies for consent processes in order to reflect and respect differences plus adhere to agreed standards of obtaining consent where they exist. Facilitating 'alternative' methods and continuing an ongoing series of interactions by thinking carefully about what is needed to respect cultural norms whilst meeting agreed thresholds is a major challenge for global research endeavours. Efforts to harmonize governance and ethics, as well as operational standards, are ongoing in both biobanking and as an explicit aim of WADA.

Consent should be understood as a process rather than a single event, a concept widely accepted in longitudinal research as respecting the need for interaction beyond a single consent transaction consent (Kaye et al, 2015; Ploug & Holm, 2017) should be understood as a process is an idea with serious implications for biobank research given the promise of long-term storage and of potential new uses, questions and applications. The traditional paper-based consent model is static, implying a 'one time ask and answer' that is then filed and potentially forgotten. Using audio visual technologies may help to improve ethical consent-seeking from populations that do not primarily communicate in writing, but may also be a method to explore for all populations as it can be inexpensive, simple to use and to store, and can readily be added to over time. This ease of use and ability to remain flexible is the basis on which dynamic consent is justified (Kaye et al, 2015). For groups where there is a perceived risk to consent being documented, consent procedures must be further adapted and refined to ensure confidentiality and flexibility. In a culture based on oral communication, there is also a potential trust issue if the researcher requires written or audio recorded consent. That is, the spoken word or verbal assurance may have more power in some orally based cultures than in the West, and therefore it can be perceived that a person's word is not sufficiently trustworthy if asked a request is made by a researcher to record it. The act of asking can be offensive in and of itself. Therefore, local guidance must be sought before

beginning consent processes. For non-writing persons in a writing culture, the use of mobile technologies has the potential to improve consent quality and to widen access to research to those who may previously not have felt able to participate. Technology may facilitate access, but it cannot replace the ethical and legal requirements to decide appropriate consent models. Next, several widely discussed and used consent models will be examined for their potential application to biobank research.

4.1 Specific Informed Consent

Individual, written, informed consent has been seen as the 'gold standard' since the beginning of modern medical and research ethics following the Second World War, and has been a cornerstone of post-war clinical research. Specific informed consent is based on protecting individual autonomy in a setting where one person receives specific information about one research use of samples and/or data that takes place at one time and in one location. As Manson and O'Neill (2017) put it, information is not 'stuff' to be passed on and therefore create consent, but a series of communications that are iterative and interactive. This conception of consent aligns broadly with the Beauchamp & Childress model, widely referred to in clinical and research consent practice:

> 'The basic elements of informed consent in the standard view are 1) Competence (to understand and decide); 2) Voluntariness (in deciding); 3) Disclosure (of material information); 4) Recommendation (of a plan); 5) Understanding (of 3 and 4); 6) Decision (in favor of a plan); and 7. Authorization (of the chosen plan)' (Beauchamp, 2017).

This model is widely perceived to offer the best protection for autonomy and as such has been transferred wholesale from clinical to data-based research. For research biobanks, however, which bring together existing data repositories, it is difficult or impossible to gain specific consent, as intended uses of the data are unknown at the time of joining. Not only might uses be unknown, but they may be in principle unknowable at any particular time in the ongoing research processes. A further problem arises in the contexts of retrospective or secondary use consent. Many biobank collections contain samples taken with consent for particular research uses and stored following that use. There is no universal approach to consent for second uses, other than it should be broadly within original parameters and with research ethics committee oversight. The Public Population Project in Genomics and Society (P3G) and Global Alliance for Genomics and Health (GA4GH) have developed guidance on

assessing ‘legacy collections’ and consent which may assist researchers in deciding what is needed to re-use samples and data for international sharing[23]. If there is uncertainty regarding the adequacy of legacy consent, researchers should consult their local ethics committee for advice regarding re-consent. They might be able to obtain a waiver from having to re-contact individuals and re-consent. If the decision is to re-contact and re-consent the participants, the Generic International Data Sharing Prospective Consent Form may be of assistance

Even in the traditional model, concerns remain as to whether participants are sufficiently informed and comprehend the known implications of engaging with research projects. For example, information may be given but not read, or read but not understood; care may or may not be taken with checking comprehension of what is being authorised. Informedness literature makes no specific reference to the healthcare practitioner checking understanding. Manson and O’Neill describe this as the ritualisation of consent and refer to the ‘communicative transactions’ required for valid consent (2007, 184). Clarity and transparency are vital to effective communication and therefore to good quality consent to research. If reduced to ritual, consent is meaningful not because it protects autonomy or is informed and voluntary, but it serves merely as a “talisman” that serves principally to authorise research, absolving further duties or liability for researchers once it has been gained (Manson & O’Neill, 2007). Consent understood in this way also authorises and shapes the research endeavour itself, which brings its own challenges[24].

The process of “consenting”, is now so ubiquitous that for many people it is simply a tick-box exercise (Dawson et al, 2019). Additionally, an assumption is made that this is something the clinician or researcher does to the participant or patient, as a passive recipient or perhaps in partnership, though this may be more challenging for the large-scale data research that is the focus of this thesis. It is commonplace to bypass reading the full terms and conditions for a website before ticking the ‘I have read and I accept these terms’ box, particularly as this may involve several pages of legal or technical information. This can lead to ritualization as described, and therefore to loss of quality and ethical rigour. In addition to the challenges to informed consent briefly noted, many of the populations from whom research consent would be sought are not patients, who can be considered as highly motivated to participate in research, but healthy athletes. Those consenting to sequencing and/or secondary use of their previously collected samples may potentially uncover disease

[23] https://www.ga4gh.org/wp-content/uploads/GA4GH-Consent-Tools-FINAL.pdf
[24] See Sheehan et al, 2019 for a more detailed discussion of the role of consent in shaping research.

risk in themselves or heritable traits that impact their families. This is not a risk that precludes non-clinical genomics, but requires pre-test counselling and considered reporting of results with further support where necessary. This burden on the participant without significant benefit to themselves or their community may weaken the case for a move from informed to broad or other less stringent consent forms in the case of population-scale research involving genetic data. For other kinds of data, however, broad consent in combination with accessible, reflexive governance and appropriate stakeholder involvement may offer a justifiable way forward.

The question of whether the traditional model of informed consent is even applicable to biobanks is a problem that has been widely discussed in the literature. The possible alternative models to specific informed consent to biobank research are discussed here. It is telling that they are considered to be alternative i.e that specific informed consent is perceived as the default. Given the increasing use of the broad consent model in biobanking, including UK Biobank, it appears that it may be seen as the default for 'minimal risk' research though what constitutes minimal risk is highly debated. Broad consent may be widely used but not without criticism from those who claim a lack of informedness, claiming that other models are more supportive of autonomy and therefore more ethically justifiable.

4.2 Broad consent

This model is widely accepted as the method of consent for biobank and population-scale research because of the flexibility of use that it allows. The traditional specific model of consent is based on one person making one fully informed decision at a time about one research use. Broad consent is critiqued for being non-specific and therefore less ethical but this is based on a presumption that the most ethical option is specific consent and that the ethical value is based on the element of specificity or detailed expression of preference. Broad consent can be informed, voluntary and well understood, therefore just as ethically sound.

There are common mistakes about informed consent- that it has to be specific consent and cannot be broader- that miss the idea that consent can be a grant of authority to govern as well as to act in ways that would otherwise be impermissible. Such authority must be based on the person granting consent being well informed about processes rather than research actions. For open-ended biobank research, this approach seems appropriate because of facilitating better quality of consent whilst retaining space for the expertise of researchers

regarding specific uses and placing a lower burden of work on participants than consent to each specific use for example. Information about proposed research should still be available, as far as it exists, but it should not be a requirement of participation that every potential participant has read everything. Respect for autonomy is met by respecting the right to give an open 'yes' if the participant so desires. This speaks to the question of who should have the authority to determine the shape and future of research and therefore what ethical role consent plays in research (governance), to shape the direction of research or to indicate engagement at an individual level, for example.

A choice may lead to informed consent even where choices are not fully autonomous- it is possible to make a voluntary choice from a list of options determined by others, but it is preferable that the determination is constructed by the (both adequately informed and relationally-situated, but free) chooser. The broad consent model proposed by Sheehan et al (2019) revisits aspects of the research governance and consent debate that have been missed in recent discussions. Broad consent has previously been too quickly set aside, perhaps because it appears technically less sophisticated than dynamic consent or because it is not quite so overtly driven by an aim of maximizing choice, such as meta consent.

Broad consent is the model currently in use in many biobanks including UK Biobank and is supported in legislative terms by the Human Tissue Act in the UK (England and Wales). It has been argued that this is not a valid form of consent because of its specificity failings, and the inability to meet the basic informational requirements of informed consent. Broad consent can be applied as consent to research within broad parameters, for example for uses relating to a set of conditions, or for investigation of how health changes occur in a population (UKBiobank, 2021). It can also be described as consent to governance, rather than directly to research. This represents a shift away from consent as the individual exercising control, or 'agent sovereignty' dependent on the specific project, to placing one's trust in a governing group and therefore giving control over to that group, properly understood and managed. In order to qualify as any kind of consent, it is argued that broad consent requires deliberation rather than just information, and as such can still respect personal autonomy via the considered choice to enter a biobank scheme and have further choices be governed by a specified body convened for that purpose. In broad consent, a person agrees to an outline of research aims, with the governance of research activities and dissemination of information to the public overseen by an appropriate governance committee, which should include participant members both in the design and running. Participants should be included in the

design of consent processes and research more broadly, but not be responsible for that design or construction of research without expert input (Sheehan et al, 2019).

4.3 Blanket Consent

Blanket consent, sometimes referred to as 'open consent', describes a model whereby consent is sought and given for all types of research, or data uses, and no further permissions are sought. It is in effect a "carte blanche". There is no specificity regarding use and no direct control by the participant over what types of research are carried out, including secondary uses of data. Of the consent models presented, blanket consent is the weakest in terms of the protection of individual interests. It may have the property of voluntariness, but not of informedness. A participant retains the right to withdraw, but this is only useful if people know what research is being carried out to withdraw from. Further limitations to withdrawal exist where data are anonymised.

Blanket consent may be perceived as justifiable where the risk is minimal, so long as sufficient protections are in place in terms of anonymity and Research Ethics Committee or Internal Review Board oversight, but all forms of consent and governance should reflect societal values. This includes not only the ways in which data might be used but also by whom. In the 'Your DNA Your Say' survey from the 100K Genome Project (Middleton et al, 2018), respondents were much less willing to allow their data to be used in commercial projects without consent for each novel use than they were for e.g. NHS led research.

Care.Data is a recent (2014) high-profile example of a population scale data project whose failure was in no small part due to lack of social approval, or licence. Uncertainty regarding the role and aims of the project and lack of trust were amongst the factors that led to failure to gain public support (Carter et al, 2015). Research depends on voluntary contribution, based on trust in non-exploitation and public benefit. Where trust is lacking and a project contravenes societal norms or expectations, such as confidentiality of GP medical records, legislating does not replace, nor can it create, social validation. As the name suggests, blanket consent is non-specific and does not allow for the expression of specific preference. In contrast, broad consent provides some greater control, specifying parameters for research being consented to, but is not as specific as informed consent (Sheehan, 2011).

4.4 Meta Consent

Ploug and Holm (2016) propose a consent model that covers research uses throughout the course of a life. They call this "meta consent". Specific types of research are consented to and

can be amended over the life course at the discretion of the participant. The basis of meta consent is that 'people should be given the opportunity to make choices based on their preferences for how and when to provide consent' (Ploug & Holm, 2016:725). Such a view places the possibility for processual understandings of consent but does not force them on the individual participant. Meta consent may protect participant autonomy by enabling a choice over the possible uses of their data. This may be more or less specific. Thus, for example, a participant may say "yes" to cancer research, but "no" to diabetes research. Equally, they may authorise use for one particular project (e.g. UK Biobank cardiac disease tissue bank) but not others. They may also be invited to elect for their data to have unspecified future use. When a participant is selective about the uses, they should be contacted when new directions or applications for the data are intended. Where a person states a preference for no further contact, they potentially miss the opportunity to take part in research in which they might otherwise have chosen. Where a person chooses to give consent to specific projects only, but requests the opportunity to consider other uses, they will need to be re-contacted for further consent. One model for this is 'dynamic consent'. We can describe meta consent as a specific approach to dynamic consent: Choice respecting, but from a pre-chosen list of options. If the justification for facilitating preference is that it is autonomy protecting, then limiting choice also limits autonomy protection. A way to partially mitigate this might be to involve stakeholders in the creation of the choices, a process that needs to be managed carefully for quality and bias.

4.5 Dynamic consent

Dynamic consent includes the option of going back to the contributor every time a new use of data is proposed. It is based on the use of technology to facilitate consent for each research use of samples or data. This reflects the clinic-derived standard of informed consent per research project, but it is not without problems. Concerns include potential 'consent fatigue' due to repeated re-contacting, as well as placing an undue burden on participants for little or no personal benefit; for example, Biobank research potentially benefiting future generations, but unlikely to have a direct (therapeutic, or example) benefit for those participating. This may affect both the numbers of people who sign up initially and lead to higher attrition over the life of the research biobank. If consent becomes routine, it loses the quality that gives it validity in the first place (Manson & O'Neill, 2007). Other questions include how distinct the new use has to be from the original use consented to require re-consent, and who decides the

boundaries for this. Dynamic consent could be utilised to facilitate a meta consent or broad consent approach as it is an adaptive method. In dynamic consent, it is not obligatory to re-contact a participant for each new use as they can choose to give broad consent covering a range of potential research uses. This further legitimises broad consent and somewhat reduces the validity of the claim to ethical superiority made by proponents of dynamic consent (Sheehan et al, 2019). Meta consent can be reasonably considered to be a form of dynamic consent although the authors of the model do not make this claim. The consent sought on re-contacting might be broad or specific, depending on the context. Ploug and Holm allow multiple changes to the specific details of the consent given by an individual. Therefore even if the scope of the choices is limited to the form that future consent will take, that choice is dynamic and can change as often or as little as the chooser wishes. Thus, meta-consent differs from dynamic consent in the sense that it focuses more specifically on allowing a person to dynamically control the kind of consent that they prefer but it is still a type of dynamic consent and therefore subject to some of the same drawbacks.

There is an underlying assumption in the dynamic and meta-consent models that deciding and designing choices about research participation should always be the domain of individual participants. This 'misconstrues the rightful location of authority in population-level biomedical research activities' (Sheehan et al, 2019: 226). The authority for determining the nature and shape of choice-making about participation in such research ought not to lie solely with individual participants, but rather with the researchers and the research governance process, and this necessarily leads to the endorsement of a broad consent approach. Both dynamic consent and meta-consent approaches seem to allow some control of the process with the researcher: meta-consent permits researchers to offer a limited range of consent models to prospective biobank participants. There the range of options have been chosen by the researchers, and not the participant who decides between pre-selected options. The dynamic consent approach seems, therefore, to somewhat restrict the dynamic aspect of the model, as choices are being made on behalf of the participant. In both meta and dynamic consent, this challenge is not fully addressed and should include an explanation of when participant choice should be limited in this way.

4.6 Waived and deemed consent

The Council for International Organisations of Medical Sciences (CIOMS) guidelines allow for waiver of informed consent for research uses where risk is minimal but does not offer a definition for minimal as it is a comparative term. There are parallels with policies of deemed consent for organ donation such as implemented in Wales from 2015 and sometimes referred to as presumed consent. A point of contrast, however, is that the specifiability of the benefit from biobank research exists as a future potential rather than a tangible good that can be pointed to at the time of consent and this may be hard to grasp for participants. By contrast, the result of an increase in organ donation is concrete and auditable. The waiver of consent in organ donation in Wales' organ procurement policy is 'soft' insofar as those aware of the preferences of the deceased may have a right to refuse the procurement, even where the donor did not make a specific objection in their lifetime (Ploug & Holm, 2017). Any policy supporting waiving of consent in the ADAMS context would need to be examined carefully for potentially coercive pressures. The challenges to consent to testing and to research (general, and with specific regard to the models implemented) for athletes in ADAMS are explored in more detail in Chapter 6.

The object concerned (e.g. an organ versus a tissue sample or data) means that the bar for consent should perhaps be lower for biobanking than for organ donation due to the respective severity and likelihood of serious harms in each case. Waived consent is, therefore, less problematic in biobank research than organ procurement in this regard. Though this may be harder to justify for sports genomics, particularly studies that are investigating genetic elements of elite performance, where there is a potential commercial gain, than rare disease research for example, which has both specific patient- groups and potential public health benefits. Although it could be argued that due to the intricate and often opaque links between clinical research and for example pharmaceutical companies and increasingly, data services, such as Amazon Web Services (AWS) who provide cloud storage for UK Biobank, all research is open to potential commercial profit. It is reasonable to suggest that any ethical framework should in part reflect the current norms of the society in which it operates. This can be challenging enough in one country but becomes considerably more complex in international governance.

4.7 The Right to Withdraw

Practically, withdrawal is limited in biobanking, as once data are anonymised and then aggregated to be linked it is extremely difficult to withdraw and may be impossible where identifiers have been permanently removed. The removal of a person or persons' information may have also a negative impact on the other samples, as the power of large biobanks is in linking datasets on a large scale. The question of why we might prioritise a person's autonomy (withdrawing) over another (remaining) where such a withdrawal affects those remaining, deserves further consideration. There are different types of withdrawal, for example UKBiobank participants can withdraw at one of three levels:

No further contact: UK Biobank would have no more contact the participant directly but have permission to retain and use information and samples already provided and to obtain and use further information from health records. This level of withdrawal has the least impact on the resource and will allow continued value to be drawn from the participant's data.

No further access: This means that UK Biobank contact the participant or obtain further information from health records in the future, but still has permission to use the information and samples provided previously.

No further use: If 'no further use' is chosen, in addition to the restrictions of the first two levels, any information and samples collected previously would no longer be available for research use. Samples will be destroyed (although it may not be possible to trace materials to effect complete destruction) and would only hold information for 'archival audit purposes' (UKBiobank). This level of withdrawal would prevent participant data from contributing to further research, but it would not be possible to remove data from research previously carried out.

The right for participants to volunteer yet also withdraw their participation in research has been considered fundamental to ethical research conduct since the Nuremberg trials (The Nuremberg Code, 1947). A recent challenge to this is the idea of moral obligation to take part in research; the future benefits to society being so great that not only is participating a contribution to the public good, but that those eligible are obliged to do so (Harris, 1995). As with the move away from informed consent, this seems harder to justify for sports than for other types of research where a direct benefit to clinical populations, as well as society more generally, can be seen. In addition to the perceived differences between sports and clinical

research in terms of obvious benefit, the moral duty to take part does not account for future-orientated omics work, but is concerned with more general medical research. It seems difficult to justify a moral obligation to participate in such open-ended future uses of biobank research information.

4.8 Consent to secondary uses

Although much research in biobanks is prospective, existing samples may be used for new research purposes and may require retrospective consent. In retrospective or secondary use studies, there is a likelihood of samples having been consented to differing standards, or potentially not consented at all. Some retrospective biobanks may rely on 'old consent' from many years previous, which may not reflect the current thinking of the individual donor, and is unlikely to have included the research uses being proposed. This poses the question of how to ensure quality of consent whilst not impeding research due to the time and cost of procedures. The consent models discussed above may offer some recourse to the problem, but do not solve it. Where secondary research aims are not consistent with those for which consent was originally given, consent for the new uses should be gained, with the exception of fully anonymised materials. If blanket consent is used then the consent requirement for new uses is removed, as the initial consent process covers all possible future uses. It is not possible to re-contact the donors of permanently de-identified materials, and regulation does not require further consent for secondary use of such materials. The secondary use of existing materials is a key challenge for e.g ADAMS and other similar collaborative projects; not only because of new uses, but also because of the differing standards and types of consent given by each partner's data contributors in the first place.

Where consent has been given to research uses of samples or data within agreed parameters, of the breadth allowed by the model of consent that is used, then uses within those parameters are allowed without subsequent consent. Secondary use refers to any use of samples or data outside of the original bounds of agreed research uses, or to research use where those items were originally collected and stored for non-research purposes, as for ADAMS. If consent has been waived or a blanket model applied then there is no requirement to seek further consent for any secondary use. Where data are anonymised, there may not be a requirement for initial or secondary use consent, depending on location and type of data. As mentioned,

the data type is not necessarily the best way to assess what level of specificity of consent is most appropriate as it may tell us something about potential risk but it alone is not sufficient to fully determine risks and potential harms. We ought also to bear in mind, the 'unknown unknowns' both in terms of potential findings and benefits, and potential hazards. Anonymisation or pseudonymisation is frequently used to protect participant privacy and allow greater access to what would otherwise be highly sensitive data. It is important to note that there is no single definition of anonymised or pseudonymised, sometimes they are used interchangeably but they are not equivalent. Pseudonymised refers to a de-identification procedure by which personally identifiable information fields within a data record are replaced by one or more artificial identifiers or pseudonyms.

Anonymised refers to data that has had identifiers removed, often permanently with no possibility for re-linking. An example of this is the SAIL database, which utilises a range of data sources including NHS health records, Office of National Statistics data. SAIL data are anonymised and access is managed via a remote safe haven or 'trusted third party (TTP)'.

No single definition of re-consent exists and there is considerable ambiguity in how it is described and used in practice. Re-consent has been used to describe activities ranging from revisiting the entire consent process, where refusal would mean a participant withdraws completely from the project (this may be limited in practice as discussed in the Right to Withdraw section) to seeking consent for a single new aspect of the project, where refusal would allow continued participation but not the new use. Wallace et al define re-consent broadly as the process of 'seeking participant consent to change or update their existing consent to allow their samples and data to be used in a different way from that which was originally agreed or to confirm that new uses fall within the expectations and understandings of participants' (2016: 211).

4.9 Conclusion

It is a mistake to simply attempt to apply the individual clinical model, designed for one person taking part in one study in one location (albeit over time and multiple interactions in some cases) to large scale aggregated data-based research that may be multi-jurisdictional and open ended- hypothesis generating rather than hypothesis-testing. This is because research uses may be in large part unknown at the time of seeking consent to participate. Public engagement may benefit from engaging with ethics as well as the content and

processes of research. This might include the bases for consent and governance approaches and should not be simply information giving[25]. Whilst important, public engagement with research and specifically research ethics and consent, is not a substitute for accessible information, quality governance and operational procedures and ethical oversight.

It is important to understand the role and function of consent including who holds the authority to construct research activity and governance (Sheehan et al 2019). We should recognise the conflation of preference expression with autonomy-protecting informed choices and separate the two. Preference respecting may appear to support autonomy but it is not sufficient, and may not always further the chooser's interests.

Consent has been understood to have differing meanings over time and in different places which is an additional challenge for longitudinal, multi-jurisdictional research with its plural settings and longitudinal chronology. The concept of individual autonomy, and certainly autonomy as a priority over other relevant ethical concerns or principles is a relatively recent Western concept that does not capture how people relate to each other in much of the world. Relational approaches may better describe the differing ways in which people conceive of autonomy and how that impacts the giving and withdrawing of consent to research, as well as issues such as disclosure and privacy[26].

Consent discussions should also include what will happen to data or samples following the closure of biobank, an under-researched area with respect to processes and ethical challenges but these are areas that merit further consideration and should be part of any future framework. Transparency and accountability as well as inclusive public engagement is vital

[25] See Chapter 7 for a more detailed discussion of the role of public involvement and engagement in biobank research and its potential role in the development of research governance.

[26] Relationalism is the idea that 'moral status is constituted by some kind of interactive property between one entity and another, which property warrants being realized or prized.' (Metz & Miller, 2016: 2). In the West, expression of relational thinking is relatively recent, though some related ideas can be seen in Marx and in the religious traditions to care for others. Relational ethics can be seen as a response to the (white male dominated) individualistic approaches and draws upon ethics of care, feminist ethics and majority world philosophies such as Ubuntu (Held, 2015; Metz & Miller, 2016; Herring, 2020).

Relational approaches do not exclude the ability to make moral decisions at the individual level, but they centre relationships and a relational account 'accords no moral status to an entity merely on the basis of its intrinsic properties. A relational theory implies that a being warrants moral consideration only if, and because, it exhibits some kind of other-regarding property, one that is typically intentional or causal' (Metz & Miller, 2016:2). This is in tension with the centring of personal autonomy and therefore the underpinnings of consent to research from individuals. However, individual consent is the current legal and ethical standard for allowing the use of personal data[26] and situating it in a relationally-aware model of applied ethics may be a compromise that enables current operational research ethics to continue, while respecting these important relational aspects of personhood.

from before the start of recruitment and continuing throughout the lifespan of a biobank or related research project.

Public involvement and engagement (PIE) is a broad category encompassing a range of possible activities and interactions. This is not an analysis of public engagement in biobanking, but an acknowledgement of its importance and limitations in the biobanking context. Public engagement and involvement and their role in governance and research are discussed further in Chapter 7, noting the importance of communication and interpersonal relations in consent processes for complex or risky research in particular. Such personal interaction is not possible in the same way for large scale population research, for anonymised datasets, or for secondary uses of existing (identifiable) data without protocols for recontact. It is however possible in smaller populations and should be encouraged in populations with some inherent vulnerability due to context, such as athletes whose data is held in ADAMS. All consent processes require effective and appropriate communication of information, which may be very complex and potentially shift over time. Communication should include checking comprehension and ensuring the ongoing nature of the consent process (Wallace et al, 2016). If a consent to governance model of broad consent is adopted then this becomes less necessary, because the participant or contributor does not need all the details of research and indeed they may not be known or knowable at the time. In this approach, it is not a problem for informedness if those details are not available, because the informing is regarding the governance and not research purposes

While consent is one of a range of ethical concerns around biobank research, it is undeniably a central one. This chapter has critically reviewed the main consent models either in use, or potentially appropriate for biobanking. For researchers, the more open the consent, the more potential research uses are available to be explored. Conversely, the more restricted the consent, the fewer possible uses without seeking further consent which brings with it further time and cost burden as well as the potential burden of work on participants of re-consent. The form of consent to be used should fit the nature and purposes of the research. Anonymity and confidentiality notwithstanding, a high degree of latitude might be thought to compromise individual consenters' interests. This is true if we consider participants purely as individuals, but if a more communitarian, society focused approach is taken then it could be argued that more open permissive models of consent in fact promote interests, supporting the right to benefit from science. Some take this further still and claim that a duty to participate

exists. This at first seems to be in direct tension with consent as individual autonomy protection, but the distinctions are more subtle.

Except for blanket consent, it seems that each of the consent types could be viable on its own terms as part of an ethical model for biobank project governance and development. The choice of consent model ought to some extent depend on, and reflect, the nature of the research being undertaken, with the level of risk being an important factor in that choice. Some flexibility seems unavoidable given that biobank development is in relative youth compared to other forms of research programmes. It appears unjustifiable to prescribe too closely the forms of consent in such a rapidly developing and complex field, particularly given the challenges of international collaboration.

Collaborative biobank and data-focused projects face challenges around linking to or adding data from existing research projects. This should be done only where it is broadly consistent with the aims to which participants originally consented. Where blanket consent was used, new future uses are technically allowable without further consent. Regulation is rendered extremely complex by the multiplicity of sources of data, and it is noted that a ‘one size fits all’ all policy is not applicable in the case of international biobank research. Ethical principles that guide tailored frameworks, rather than a single set of regulations, may be more helpful in conjunction with the use of technical privacy and security measures such as federated access, differential privacy and Trusted Third Parties (TRE) as practical safeguards that enable data usage for societal benefit in ethically justifiable ways.

The considerations surrounding consent raised in this chapter should contribute to the understanding of ethical and regulatory practices by considering how to meet the challenges of governance in the context of biobank and data research. For these reasons as well as those that apply to biomedical research more generally, it is important that new biobank research groups embed robust ethical and regulatory practice in their infrastructures before initiating procedures to access data collections. The careful consideration of underlying norms that inform how consent and other challenges for governance are conceptualized is vital to maintaining constructive relationships with data contributors. It also helps to illuminate ways in which data can be shared in a manner that is both ethical and supportive of the research aims. Appropriate consent is one of a suite of measures is key to developing and sustaining the success of collaborative biobank research and a key element of recommendations made

for the potential future use of ADAMS data[27]. ADAMS is a special type of biobank in that samples and data were originally taken and stored for non-research and non-medical uses and as part of mandated doping controls. Therefore, we must identify specific challenges and then offer tailored recommendations (Chapter 6). To provide contextual background for this work, the next chapter locates ADAMS in the anti-doping movement within global sport.

5 Anti-Doping

5.1 Introduction

This chapter will define key terms, briefly outline the development over time and current landscape of the global anti-doping movement in sport. It will identify the main stakeholders and key instruments in doping control including the development of the World Anti-Doping Agency (WADA). Doping control, including what should count as anti-doping rule violations (ADRV), and how to approach prevention and sanctions and the bases on which doping control is justified, is the subject of a dynamic and wide-ranging ethical, political and scientific debate. Approaches to doping control, as well as what methods and substances should be prohibited are not universally agreed upon. However, all those whose sporting activity is governed by bodies that are signatories to the Code, most visibly but not exclusively those who compete in elite sports, are obliged to adhere to the WADA Code and International Standards (IS) including the prohibited list, and the requirements that follow from it, administered by official sporting bodies.

This work briefly examines the rationale for anti-doping measures and how the world of doping control operates but does not engage with the debate about defining doping and enhancement. It will briefly consider the relationships and power structures between the stakeholders in terms of how that may impact decision-making and policy implementation as this is relevant to a discussion of potential future research use of athlete samples and data. It is not the intent to debate whether current definitions of doping are justified or not but to contextualise the setting for the ADAMS biobank and activities relating to doping control and associated research. For the purpose of this work, it is assumed that the position that doping, as it is currently understood and defined by WADA, is harmful and requires control is essentially correct. Where ‘sport’ is referred to the term includes para and non-para sports.

[27] See Chapter 8: Conclusion for recommendations. S.8.1 for summary table.

The practice of taking substances and/or using methods, equipment to enhance sporting performance is not new, nor is the idea that some actions undertaken to produce an advantage may be considered cheating and therefore should not be allowed in competition. There follows a brief overview of key developments leading to the current anti-doping systems and approaches. This background is offered in order to locate the ADAMS resource, owned and operated by WADA, in the context of global sport and to reflect on how that context influences the ethical and governance challenges associated with allowing research access to ADAMS data.

The modern Olympics began in 1896 in Paris and in 1928 the International Amateur Athletic Federation (IAAF, now World Athletics) officially prohibited the use of enhancing substances in athletics competition for the first time. (Hunt 2015). Then in 1938, the International Olympic Committee (IOC) produced a resolution on amateur (athlete) status. While the use of stimulants had been publicly discouraged since the 1920s, Article 6 of the resolution was the first official regulation for all sports disciplines at the Games (Hunt 2015). The 1948 Olympic Games was the first event to implement the resolution.

> 'Article 6 – Doping of athletes: The use of drugs or artificial stimulants of any kind must be condemned most strongly, and everyone who accepts or offers dope, no matter in what form, should not be allowed to participate in amateur meetings or the Olympic Games' (IOC, 1946).

The next major addition to anti-doping regulation came in 1960, following the Rome Olympics. A Danish cyclist Knud Enemark Jensen died from a heatstroke before completing his event and a crisis emerged (Hunt 2015). It was claimed that Jensen had been using amphetamines, or 'pep pills' although this was never conclusively proven. It has since been suggested that Jensen's death was used to further the growing anti-doping moral narrative and should be noted that at the time there was no testing for, or ban on, the substances he was supposed to have taken (Dimeo, 2016). When another cyclist died in 1967 during a late stage of the Tour de France, the pressure on the IOC to act increased. In this case, traces of amphetamine were present in Simpson's body, and tablets were also found on his person (Hunt 2015). In the same year the first Council of Europe document regarding sports: Resolution (67)12 on the doping of athletes' came into force.
(https://www.europewatchdog.info/en/doping/).

During this period France and Belgium created anti-doping regulations, and international federations also officially prohibited doping. The new IOC medical subcommittee on doping established a regulation on doping that included the first list of banned substances- now the

annually updated WADA Prohibited List- outlined new testing procedures and a system of sanctions for those who were caught (Hunt 2015). The regulation applies the same conception of the amateur provided by the IOC and has been critiqued as a reflection of the upper class background of decision makers and many Olympic athletes at the time (Henne 2009,2014). As well as medical harms, it included reference to the purity of sport and the idea that athletes should be protected from harmful practices. The first doping tests were administered at the 1968 Olympics in Mexico City, setting a precedent that can be seen in current practice and the importance of supporting independence in research:

> 'The scientists who pioneered anti-doping established a logic which remains with us today: if society wants 'clean' sport then we need the resources to achieve it; and we can do so by promoting research into testing and increasing the extent of testing' (Dimeo, 2016: 105).

The post-World War Two period saw the rise of the Cold War, prompting countries to vie for the highest honours in sports in order to prove their superiority. Doping would prove part of the means to achieve distinction. The most well-known example of this political drive to succeed in sport is probably the East German doping program of the 1970s and 1980s known as 'State Plan 14.25' (Dennis 2015). For the German Democratic Republic (GDR), achievement in elite sports was a way to acquire both validation at the international level and create stability and control at the national level. Hunt describes State Plan Theme 14.25 as a "massive state-sponsored initiative overseen by some 1500 medical personnel, coaches, and sports scientists" (2015: 212).

Commencing in 1972, thousands of athletes were included in the systematic doping program, and, likely, the true figure will never be publicly known. Not only did the state endorse the use of performance-enhancing drugs (PED) and methods, it worked on developing drugs and methods that could evade detection by existing tests. Athletes were given a range of substances including amphetamines, Human Growth Hormones (HGH), exogenous testosterone, and erythropoietin (EPO) although anabolic-androgenic steroids were the most common, and high profile (Dennis 2015). Substances were given to athletes, including minors, often in high doses and often against the directives of the GDR's own medical staff (Dennis 2015). The program continued in some form until the fall of the Berlin wall in 1989 and the subsequent reunification of Germany, with athletes learning, sometimes many years after the fact, of significant risks to their health and that some conditions that had experiences were proven or very likely side-effects associated with the PEDs they had been given (Dennis 2015).

During this period, individual athletes were penalised for doping if they tested positive for an illegal substance, but the GDR program itself continued. It was geopolitical shifts rather than primarily anti-doping measures i.e. the fall of the Berlin Wall and the collapse of the USSR, that caused the program to fold.

While the GDR set-up may have been the most well-known and systematised, other satellites of the USSR (and the USSR itself) used similar methods to gain an advantage in competition (Lunqvist, 2017). Western countries also saw increased doping, during a period when a sporting loss to communist states was considered high stakes and to be avoided on political as much as competitive grounds. Such nations therefore appeared to 'turn a blind eye to potential transgressors on their own teams' (Hunt 2015:212). An example of this is the 1980 Moscow Games, where no cases of doping were detected, but a significant number of positive results re-surfaced during record checks afterwards. Some experts believe that up to twenty per cent of athletes should have been found guilty of doping, a large percentage of those from testosterone use (Hunt 2015; Dennis 2015). The East German example showed the public that the choice of doping was not solely an individual one and that the idea of a 'lone', immoral cheating athlete was a misperception. Having some knowledge of the historic and present complexities that exist in sport and doping control is important for developing context-appropriate ethical governance. The influence of sport's past with doping and in particular the systematic practices of large organisations and even states, is reflected in the later inclusion of support personnel in the Code and sanctions. The potential for (and multiple high-profile cases over several decades) systematic doping at individual, team or national level has continued to inform the development of anti-doping regulation and led to the inclusion of athlete support personnel and sporting organisations as liable for seven out of the eleven anti-doping rule violations stated in the Code.

The Code is the core document for WADA and is based on the Anti-Doping Convention (CETS No. 135) The Council of Europe's Anti-Doping Convention entered into force in 1990 and has been ratified by all Council of Europe member states. It lays down binding rules intending to harmonize anti-doping regulations, in particular:

- making it harder to obtain and use banned substances such as anabolic steroids
- assisting the funding of anti-doping tests
- establishing a link between the strict application of anti-doping rules and awarding subsidies to sports organisations or individual sportsmen and sportswomen

- regular doping control procedures during and outside competitions, including in other countries

A key driver for the explicit harmonization of anti-doping regulation and practices was the lack of consistency and international oversight that previously existed. Even following the development of WADA and its systems, there have been striking examples of organisations who have broken the rules and been exposed as complicit or even driving, rule violations. A high-profile and large scale example of this is briefly outlined below to demonstrate the complexity of the anti-doping and sporting world, and how it relates to broader geopolitical movements, analogous with global research efforts.

The exposure of Russia's state-sponsored doping scheme in 2016 revealed a contemporary system of state protection shielding doped athletes from tests in international competitions. WADA handed down a four-year ban on athletes competing under the Russian flag and withdrew accreditation from RUSADA (Russia's NADO) for the same period. On appeal to the Court of Arbitration for Sport (CAS) in 2020 the ban was decreased to two years, a decision that was widely criticised for being too lenient and for undermining efforts to improve doping culture at national level. The Russia case is highly complex and longstanding and will not be discussed in full here, however its influence can be seen in a number of ways including the introduction of the whistleblowing related ADRV in the 2021Code (WADA, 2021c). It also serves as an example of why harmonization of regulation and its application is so important to WADA and the same principle should apply for the regulation of research with ADAMS data.

The above is a brief history of doping and the anti-doping movement, offered with the aim of demonstrating how the development of current anti-doping movements arose out of a pattern of relative stability or inaction interspersed with moments of crisis and change-driving events. Such a pattern can be described as punctuated equilibrium, a term originating in palaeontology (Eldredge, 1985; 2014). Anti-doping policy can similarly be characterised as reactive (Read et al, 2019; Ritchie, 2014); responding to a particular scandal or stakeholder desire to increase or consolidate power. 'In the absence of crisis, issues often have difficulty moving beyond the early stages of the policy process' (Hunt 2015, 210). This characterisation does not disregard proactive work in local contexts but refers to the overall approach of the movement in adapting to events that occur and the prioritisation of compliance with the Code for all stakeholders. Taking a proactive or locally optimised approach may be more difficult

if compliance is equated with effectiveness. This is true for both doping control policy and for policy in research.

Given the global nature of sport and the number of organisations and roles involved, as well as multiple competing interests including commercial, political and nation-states, there existed a complicated and fragmented range of approaches to combatting doping. Added to this the ever-increasing sophistication of doping methods seeking to evade detection, made easier by the lack of leadership and coordination in anti-doping at the time. In 1963, The first official definition of doping was given by the European Committee Council stating that "Doping represents the use of physiological mediators or substances which are not normally present in the human body but are introduced as an external, during a competition, aid to increase the athletes' performance' (Vlad et al 2018). This definition has since been expanded to include methods and the strict liability offence of anti-doping rule violation (ADRV) was introduced, based on criteria set out in the core instruments of the World Anti-Doping Agency (WADA).

5.2 Organisations

Organisations responsible for managing doping control including testing and results, enforcement in their respective areas of interest include the IOC, International Paralympic Committee (IPC), International Federations (IFs), National Olympic Committees and Paralympic Committees, Major Event Organizations (MEO), and National Anti-Doping Organizations (NADOs). These organisations are referred to by WADA as Anti-Doping Organizations (ADO). 'All provisions of the Code are mandatory in substance and must be followed as applicable by each Anti-Doping Organization and Athlete or other Person' (WADA, 2021b:12). To date approximately 700 organisations are signatories to the Code. In order to meet the requirements of signatory, organisations must demonstrate 'acceptance, implementation, and enforcement' (of the Code) (WADA, 2021).

International Federations (IF) are not-for-profit associations that govern a sport at international level. They are among the most important stakeholders of the Olympic system which is central to global sport, together with the IOC, the National Olympic Committees, and the Organizing Committees of Olympic Games. Each IF has the right to govern a specific sport. For example, the International Surfing Association (FIFA) oversees competitive

surfing globally, has been a signatory to the Code since 2003 and adopted a Code compliant anti-doping programme in 2019 ahead of the sport's first Olympic qualifying event (WSL Championship Tour 2019, for the- postponed-Tokyo 2020 Olympiad). ISA is an interesting case because of the nature of surfing as a sport and the clear relationship between introducing anti-doping measures and the bid to qualify for inclusion in the Olympics. That combination may not be exclusive to surfing but ISA is a recent and high profile addition to the Olympic line up. IFs host their own profit-generating championship events, for example the WSL Championship Tour in surfing, and therefore have financial independence to a greater or lesser extent. Smaller IFs whose sports do not have large audiences outside the Olympic Games may depend more on the television income of the Olympics and therefore be more dependent on the wishes of the IOC compared to those that have higher non-Olympic incomes(Ritchie 2020). As a further complication, some organisations have more than one function or classification in relation to doping control. For example the IPC functions both as an International Federation (IF) and a Major Event Organisation (MEO). These are just two aspects of the complex financial and political relationships, given as examples of why 'independent' is a contested term in the anti-doping context and sport generally. A detailed discussion of the motivations for doping controls in sports, beyond fairness and health concerns, is beyond this overview however underlying ideologies, the mandatory nature of doping control measures and compliance with regulations has the potential to colour the athlete's relationship to their doping control information and data generated by the processes. The impact of these factors along with the athlete-WADA relationship will be discussed in Chapter 6.

5.3Therapeutic Use Exemption (TUE)

Under specific circumstances, substances that are on the prohibited list, including threshold substances (those allowed up to a certain dosage, above which a positive test would be a rule violation), may be allowed for therapeutic use. The ISTUE is the governing document for TUE with the aim of harmonizing the TUE application and management processes across sports and nations to ensure clarity and enable compliance. There is a suite of checklists and other guidance to support decision making and these are 'living documents', based on the Code and updated according to changes in (medical) best practice (WADA, 2021).

TUE guidance lists common medical conditions, but any medical condition can be considered based on the ISTUE. TUE decisions can be controversial and there is ongoing debate around the principles and their implementation (Hämäläinen et al, 2020). TUE is mentioned here as an example of doping control processes that create data to be stored in ADAMs and can be described as both medical and doping related data for the purposes of governance. This hybridisation of doping and health or medical data may have significance for research uses in general and in particular potential secondary uses beyond anti-doping. The implications of athlete data type and categorisation for potential research use are explored further in Chapter 6.

5.4 The World Anti-Doping Agency (WADA)

WADA was created in 1999 by the International Olympic Committee (IOC), national governments, and sporting bodies, with the stated aim of offering a solution to the worldwide problem of doping in sports (Hunt, 2015) and based on core values of 'integrity, openness and excellence' (WADA, 2021). The creation of WADA occurred following a series of events and previous initiatives, detailed above but the Festina crisis during the 1998 Tour de France which highlighted the failings of the International Olympic Committee's (IOC) war on doping was a particular catalyst (Hunt, 2015).

WADA was tasked with creating a binding framework for anti-doping policies, rules and regulations, the cornerstone of which is WADA's World Anti-Doping Code (The Code). From the outset, WADA has been funded jointly by nation-state signatories and the Olympic Movement. National Anti-Doping Organisations (NADO) are state-funded and usually politically independent, though the extent and limitations of that independence vary (McNamee, 2012). The first edition of the Code came into force in 2004, having been adopted in 2003, and has since been amended four times, the latest version taking effect from 1st January 2021. WADA's role in leading anti-doping efforts was affirmed by UNESCO's International Convention Against Doping in Sport (The Convention) adopted in 2005, entering into force in 2007, which legally binds signatory countries (signatories) to promote and enforce the World Anti Doping Code. Both the Code and the Convention are described in more detail in Section 5.3.

WADA's highest governing body, the Foundation Board, is made up of equal representatives from the Olympic Movement and public authorities. The Executive Committee is delegated by the Foundation Board to run WADA's activities and administration and also has IOC and public authority members (WADA, 2021). As yet there are no current athletes in either group.

When created, WADA's main mission was to provide a worldwide fight against doping by "(1) increasing the risk of catching athletes who dope; and (2) standardizing the different anti-doping regulations and sanctions for doping use" with reference to a central vision of "[a] world where all athletes can compete in a doping-free sporting environment" (Tamburrini, 2006: 200)

Today, WADA's aims, described by the Code, are broadly aligned with the IOC's previous regulations on doping and describe an ideal world for 'clean sport':

> 'To protect the athletes' fundamental right to participate in doping-free sport and thus promote health, fairness and equality for athletes worldwide, and to ensure harmonized, coordinated and effective anti-doping programs at the international and national level with regard to detection, deterrence and prevention of doping" (WADA, 2015).

Ever since the IOC resolution regarding amateur status, and the following development of more precise testing, harmonizing of regulations and sanctions, the global effort has been with the overall aim of eradicating doping altogether, in order to preserve 'clean' sports, regardless of whether that is a realistic, achievable objective (Dimeo 2016). This includes banning substances that are difficult to test for and those that are not performance enhancing, but the taking of which is deemed contrary to the spirit of sport.

The cost of running WADA and its operations is assumed by the IOC and signatory national governments. This funding arrangement has been discussed in the anti-doping ethics literature as a potential challenge to WADA's stated independence (Chappelet et al, 2018; Read et al, 2020) . The agency is responsible for certifying the NADOs and ensuring compliance (including their laboratories, used for test analyses and research). Once this is completed, NADOs are responsible for carrying out doping control functions in their areas (World Anti-Doping Agency, 2016).

Signatories to the Code are the international sports federations, NADOs, professional leagues, the IOC and the International Paralympic Committee (IPC). The North American professional leagues – Major League Baseball (MLB), National Basketball Association (NBA), National Football League (NFL) and the National Hockey League (NHL) have their

own anti-doping regulations and do not submit their players to WADA's requirements (World Anti-Doping Agency, 2016).

In 2012 the 'Doping as a Public Health Issue' symposium addressed doping in sport as a public health[28] issue. The then WADA Director General referred to a perceived 'trickle-down effect' consumption of performance enhancing drug (PEDs) and other forms of doping by elite athletes may have on minors and recreational sports, citing the health risks associated with many prohibited substances (World Anti-Doping Agency 2012). Howman stated that 'None of these matters really fall under our express mandate of elite sport, but evidence of all has come to our attention, and all provide significant issues for society in general' (WADA, 2012). This appears to be a direct reference to a public health justification for doping controls, which also places the idea in tension with 'our express mandate of elite sport'. The symposium, attended by the WHO, UNESCO, INTERPOL, the IOC and WADA, expanded the discussion of doping beyond elite sport to a broader conception of sport including recreational athletes. It called for 'significant and ongoing collaboration between those organisations and national governments to eliminate the harms of doping with regard to global public health' (World Anti-Doping Agency 2012). This included a move towards intelligence gathering and cooperation with international law enforcement agencies, recognising the trade in prohibited and illegal doping substances as significant and part of a wider criminal problem. Reference was made to doping as a public health issue and the increasing sophistication of methods and substances being developed in order to avoid detection has significance for the justification and funding of anti-doping (and related) research. The argument has been made that the banning and zero tolerance approach to doping control may in fact drive developments in doping and lead to increased competition of who can dope most effectively in terms of remaining undetected i.e. who has the resources to fund such activities, rather than deterring doping altogether (Gleaves & Christiansen, 2019).

[28] Traditionally, public health has been associated with state powers concerned with e.g., infectious and communicable diseases, mandated testing or screening, quarantine, vaccines and obligatory notification (Knoppers, 2009).
Public health is a form of social medicine, attentive towards the health of populations, 'aggregated bodies instead of individual bodies' (Lupton, 1995: 2). It is multi-disciplinary and grounded in the idea that the state is (and should be) concerned for the health of its citizens, a benevolent paternalism approach. Whilst public health is based on social, population level concerns and acts at the group level through policy, testing and vaccination programmes (The ongoing COVID-19 pandemic being a prime example both of public health actions and the adverse outcomes that can arise when a society does not maintain their public health system). Public health is concerned with societal outcomes but is often heavily focused on the individual with regard to responsibility and expectations of behavior change.

There has been increasing support and funding from WADA for intelligence and information sharing to work alongside traditional testing methods and prevention work. As athletes and associated persons who chose or were coerced to dope become more and more sophisticated in their methods, often facilitated by their support personnel, the prioritisation of intelligence gathering, calls and support for whistleblowing, and cooperation with law enforcement and intelligence agencies such as Interpol has continued. This raises a number of ethical concerns around the sharing of information with law enforcement, the risks to athletes in countries where doping is criminalised, lack of protections for whistleblowers, amongst others. The concern most relevant to this thesis is the potential use of ADAMS data for intelligence purposes and the possible abuses or harms that might follow. These concerns may be especially relevant for those athletes from nations where doping is criminalised. Concern remains regarding possible surveillance uses of ADAMS data and the associated legal implications as well as the potential to deter athletes from allowing research uses of their data.

At the time of writing, this is speculative and work should be done to gauge athlete feeling on the intelligence uses of data and in particular around any concerns that wider research access might lead to law enforcement and intelligence agencies having greater access to their information. This should be done in conjunction with work to establish WADA's intentions and the scope of their responsibility for data uses once access is allowed (See Chapter 6 for further discussion of this). Intelligence and other doping-related uses of athlete data are justified on the grounds of protecting athletes and promoting integrity in sport. Below is a brief outline of the ADA'S rationale and the World Anti Doping Code (WADC), the key instrument that underpins the global anti-doping regime.

WADA (2021) states that

'Anti-doping programs seek to protect the health of Athletes and to provide the opportunity for Athletes to pursue human excellence without the Use of Prohibited Substances and Methods. Anti-doping programs seek to maintain the integrity of sport in terms of respect for rules, other competitors, fair competition, a level playing field, and the value of clean sport to the world'.

It goes on to state that

> 'the values we find in and through sport, including: • Health • Ethics, fair play and honesty • Athletes' rights as set forth in the Code • Excellence in performance • Character and education • Fun and joy • Teamwork • Dedication and commitment •

Respect for rules and laws • Respect for self and other Participants • Courage • Community and solidarity'.

As mentioned, the core document aimed at harmonizing doping control and on which all Code signatories are obligated to base their in-house rules and guidance, is the World Anti-Doping Code, key features of which are outlined below.

5.5 The World Anti Doping Code (The Code)

Following a UNESCO convention, signed by nearly all nation-states in the world, the World Anti-Doping Code came into effect in 2004.

> 'The Code was established, not only to protect the athletes' fundamental right to participate in doping-free sport but also to ensure harmonized anti-doping programs at the international and national level' (WADA, 2021).

It is the

> 'fundamental and universal document upon which the World Anti-Doping Program is based. Its purpose is to advance the anti-doping effort through the universal harmonization of core anti-doping elements. It is intended to be specific enough to achieve complete harmonization on issues where uniformity is required' (WADA 2021).

This reference to complete harmonization at the same time as uniformity implies a not uncommon conflation of harmonization with standardisation. That is not to say that standardisation of some specific issues and approaches to them is necessarily unwarranted, but that harmonization and standardisation are not the same and therefore it is misleading to use them interchangeably. A more detailed consideration of harmonization and its application in international regulation and ethics is given in Chapter 4. Moving on from the aspects to approached uniformly, WADA states that the Code need be 'general enough in other areas to permit flexibility on how agreed-upon anti-doping principles are implemented': this second part being closer to the stated aim of harmonization with respect for contextual differences.

The Code applies to the international federations and other signatories, not directly to athletes who are governed by the legislation of their respective NADOs and sporting federations, in turn governed by the Code (McNamee and Tarasti, 2010). The Code, which exists in the sphere of private law, which refers to law governing relationships between

individuals and companies or organisations, for example contract law, property law, is added to the independent public laws of countries where athletes are training and/or competing. Signatory nations that have made doping illegal may impose other sanctions on their athletes in addition to those found in the Code (McNamee and Tarasti 2010). A relatively small number of countries have criminalized doping and most statutory law addresses doping indirectly, if at all, through legislation against drug-related activity for example trafficking, fake pharmaceuticals. These can be important tools in international anti-doping work. Investigation, intelligence gathering and cooperation with cross-border law enforcement agencies are all undertaken by and for WADA. There can be tensions between legislative sanctions and the sanctions for violating anti-doping rules in the Code. This is one limitation to the explicit aim of harmonization of anti-doping approaches that is central to WADA's mission.

Harmonization requires clarity and the foundation of core principles that are accepted by relevant parties and applied in local contexts. To this end, WADA provides a definition of doping that does not set out to fully explain doping as a concept but takes the form of a list of acts that could be punished under the regulations in the Code. The list of acts, officially called Anti-Doping Rule Violations (ADRV), is provided on p107.

This inclusive, rule-based design is not a coincidence (Schneider, 2015). It gives the Code, and Prohibited List, the final say on the substances and methods that count as doping and it frames activities linked to doping practices not only as violations of the Code but acts of doping in and of themselves. One example is that association with a person serving a ban for an ADRV is not simply breaking the rules but is specified as an ADRV itself. WADA has chosen not to provide a conceptual definition of doping. Whilst this may not be the whole rationale, not doing so avoids being at the mercy of shifting conceptions of enhancement and other aspects strongly debated in a multi-disciplinary, evolving literature and beyond. By setting out doping as infraction of rules contained in the Code, WADA maintains control on what doping is for operational purposes, and does not have to change the definition every time a new technique or substance is developed, but can respond with changes to the Code, in particular the Prohibited List and the ADRV list. This retention of control over doping in the actionable sense therefore includes some flexibility, reflected in the description of the Code as a 'living document'. However, the lack of clarity around a 'philosophically defensible definition of doping' (Schneider, 2015: 9) creates challenges for discussions on the problem of doping, and ethical issues arising from it. The Code and its definition of doping through ADRV is at the heart of global anti-doping efforts, but has no legal force and no mandate

beyond Code signatories. The Code should be considered in conjunction with the UN Convention on Doping in Sport.

The Code is a non-governmental document and only applies to sporting bodies, of which athletes need be members in order to compete at the highest levels. The UNESCO Convention against Doping in Sport (The Convention), provides the 'legal framework under which governments can address specific areas' (UNESCO, 2005). The Olympic Charter and the International Convention against Doping in Sport, adopted in Paris on 19 October 2005 both recognize the 'prevention of and the fight against doping in sport as a critical part of the mission of the International Olympic Committee and UNESCO, and also recognize the fundamental role of the Code '(WADA, 2021:8). The UNESCO Convention came into force in 2007. It has been described as the most successful convention in the history of UNESCO in terms of speed of ratification after adoption and the number of signatories. Additionally, the Anti-Doping Convention is the second most ratified of all UNESCO treaties- 191 states parties' signatories- demonstrating the global will to curb doping in sport or at least to show alignment with the powerful states that drive such efforts. The Convention is governed by the Conference of Parties (COP), which meets biennially and is made up of representatives from States Parties and other Member States of UNESCO. WADA is invited as an advisory organization to the Conference. The IOC, the International Paralympic Committee (IPC), the Council of Europe (CoE), the Intergovernmental Committee for Physical Education and Sport (CIGEPS) and other intergovernmental sports organizations are invited as observers (UNESCO, 2021).

The Convention aims to help harmonize international anti-doping legislation, regulations, and rules 'in order to provide a fair and equitable playing environment for all athletes'. States Parties commit to:

> 'encourage international cooperation to protect athletes and the ethics of sport; limit the availability of prohibited substances and methods by combating trafficking; facilitate doping controls and support national testing programmes; encourage producers and distributors of nutritional supplements to establish 'best practice' in the labelling, marketing, and distribution of products which might contain prohibited substances; support the implementation of anti-doping education programmes; and promote anti-doping research' (UNESCO, 2005).

Governments have some flexibility in how they can implement the Convention at a national level, for example through legislation, policies, regulatory practices. This deliberate freedom is important in recognising and working within local contexts, complementing the Code in mandating certain actions and approaches but allowing national and international organisations to adapt to their specific needs. In practice, many of the anti-doping policies and regulations are essentially identical to the Code, but implementation varies more widely .

The Code is drafted ‘giving consideration to the principles of proportionality and human rights’ (WADC, 2015). On drafting the first version of the Code in 2003, WADA committed to ensuring that the Code would be a living document, subject to periodic review. The Code is the core document harmonizing policies, laws and regulations, anti-doping in sport organizations and among public authorities throughout the world. It works in conjunction with eight international standards. The prohibition on doping is justified in a number of ways and a detailed discussion of the debate surrounding such is beyond the present scope, but justifications include health, spirit of sport neither of which have universally agreed definitions and both are the subject of much debate in the context of doping control.
The Code is supported by eight International Standards (IS) that aim to foster consistency among anti-doping organizations in various areas. (World Anti-Doping Agency 2021). Each standard details a different technical area:

The International Standards (IS)

- The International Standard for Testing and Investigations (ISTI)
- The International Standard for Laboratories (ISL)
- The International Standard for Therapeutic Use Exemptions (ISTUE)
- The International Standard for the Prohibited List (The List)
- The International Standard for the Protection of Privacy and Personal Information (ISPPPI)
- The International Standard for Code Compliance by Signatories (ISCCS)
- The International Standard for Education (ISE)
- The International Standard for Results Management (ISRM)

(WADA, 2021)
Relevant IS are referred to throughout, but a full discussion of all eight standards is beyond the current scope. The Prohibited List is the highest profile of the International Standards.

This list sets out exactly what drug or method counts as doping for the duration of the current version. The list is prepared by WADA's Health, Medical and Research Committee, publishes following expert consultation and several months before becoming current in order to allow for any adjustments to procedure and for athletes and their support teams to become familiar. The Prohibited List has been updated annually since 2004, the latest version coming into force in Jan 2021 (World Anti-Doping Agency, 2021).

What is doping?

Doping is defined as committing an anti-doping rule violation (ADRV) according to the current version of the Code. From the 1st January 2021 the standing definition is: 'Doping is defined as the occurrence of one or more of the anti-doping rule violations set forth in Article 2.1 through Article 2.11 of the Code' (WADA, 2021c).

The Code lists 11 ways of committing an ADRV (WADA, 2021). These include evading, refusing or failing to submit to doping control measures, being complicit in an ADRV or trafficking. Commonly, doping is understood to be the presence of a drug or other banned substance, though the Code states that a range of actions and omissions count as an ADRV and may therefore lead to sanctions. 'Doping is fundamentally contrary to the spirit of sport and the protection of Athletes' health and right to compete on a doping free level playing field' (WADA, 2021:8). A new ADRV has been added to protect whistleblowers and includes the offences of discouraging reporting of information (relating to doping) and retaliating against someone who reports. Additionally, the offence of tampering now includes tampering with results management as well as testing, for example falsifying paperwork (UKAD, 2021)

All 11 rule violations apply to athletes and seven (in italics) also apply to athlete support personnel. They are listed here in contracted form but the full version can be found in Article 2 of the 2021 Code.

- Presence
- Use or Attempted Use
- Evading, refusing or Failing to Submit to Sample Collection
- Whereabouts failures
- *Tampering or attempted tampering*
- *Possession*
- *Trafficking or attempted trafficking*

- *Administration (i.e. without aiding or abetting)*
- *Complicity or Attempted Complicity*
- *Prohibited Association*
- *Acts by an Athlete or Other Person to Discourage or Retaliate Against Reporting to Authorities*

(WADA, 2021c)

ADRVs are classified as

1. Analytical: presence of a substance found on the Prohibited List detected in a blood or urine sample given by an athlete and tested following WADA procedures.
2. Non-analytical: does not relate to an adverse test result but refers to the other actions and omissions that count as rule violation in the Code. For example complicity in the use or attempted use of a prohibited substance by another person.

Sanctions range in severity from a reprimand through two and four year bans up to a lifetime ban from competition and may be applied to individuals or organisations. A high profile and complex example of an organisational sanction is the four-year ban on Russia competing in or hosting major sporting events (as defined by WADA). The term was reduced to two years on appeal to the Court of Arbitration for Sport, a decision widely criticised by other NADOs and stakeholders in sport. Russia remains ineligible for major sporting events (but may compete in those outside the WADA definition) until 2022, however athletes proven to be 'clean' may compete under a neutral flag. There is not scope to analyse the Russia case in detail here, but it is mentioned as an illustration of the complexity and political volatility, and potential for anti-doping regulations and sanctions to have a significant and far reaching impact beyond sport. And perhaps more fundamentally, to illustrate how sport and international competition cannot be considered in isolation from geopolitical and public, global health considerations. This therefore also applies to research uses of data that arise in the pursuit of doping-free sport.

ADRVs are published and all international athlete support personnel subject to a ban, or who have been in the last six years, are listed (WADA Prohibited Association List, 2021), however there is scope not to name people for example vulnerable persons and/or recreational athletes. The inclusion of an option not to name those considered more vulnerable indicates an awareness of the potential harms of publishing ADRVs. This reflects the punitive and preventative aspects of anti-doping policy: publication of infractions is both a shaming of the offender and in theory at least, a deterrent to others.

There are a number of ways in which sanctions can be reduced, for example where an individual voluntarily admits an offence (where no evidence is given), or accepts the ADRV and associated sanction within a specified time frame. There is also a 'no fault or negligence' mitigation however this is rarely used. More common is 'no significant fault'. Partial suspension of a ban is available where the individual accused provides 'significant assistance' that leads to another person being charged with an ADRV, criminal offence or other violation listed in the Code. The 'substance of abuse' process introduced in the 2021 Code provides for shorter bans where it proven that the athlete consumed the substance(s) out of competition and was unrelated to sport. Cannabinoids are a high-profile example of a substance that is not performance enhancing, and the use of which is increasingly socially accepted, but remains illegal to purchase and to consume in many countries that are Code signatories. Use of cannabinoids carries a four-year ban, which may be reduced to three years.

The addition of 'substances of abuse' to the list acknowledges the existence of addictions and problems with drug misuse in athlete populations as part of wider society and reflects WADA's increased emphasis on health as a basis for doping control. Some kinds of ADRV may be better known to the public than others but they all carry equal weight in terms of violating the Code and therefore potentially leading to a ban on competing or other sanctions. Individuals facing an ADRV charge have the right to a hearing. In the UK for example, the National Anti Doping Panel (NADP) hears cases and decides whether or not an ADRV has been committed and recommends sanctions. The general timeline for ADRV is set out below, noting that due to the internationally harmonized but locally controlled process there may be some variation.

Example ADRV Timeline

- Appropriate body reviews the evidence and determines if there has been a possible ADRV
- Individual is notified and invited to provide a submission within a specified time
- Appropriate body claims a possible ADRV
- Individual, sporting body and international federation is notified of the possible ADRV

- Appropriate body makes a recommendation to the sporting body regarding consequences or sanctions
- the individual may then accept or contest the infraction.
- (Appeals to the national tribunal body e.g. NADP Appeal Tribunal, or to the Court of Arbitration for Sport).

The Court of Arbitration for Sport (CAS) is an institution independent of sporting organisations and WADA, which 'provides for services to facilitate the settlement of sport-related disputes, through arbitration or mediation, by means of procedural rules adapted to the specific needs of the sport world' (WADA, 2021; https://www.tas-cas.org/en/general-information/index/)

Objection to doping is primarily based on the grounds that it is unfair, deceptive and a form of cheating. This is based in the principle of the 'spirit of sport', noting that 'to cheat is to use deceptive methods in order to gain an advantage that might otherwise be unmerited' (Bloodworth & McNamee, 2017) which allows for methods, omissions, for example missing tests, as well as the presence of PEDs and other prohibited substances.

It is important to note that not all ADRVs are necessarily intentional. Intent is not required for a rule violation to occur, because doping is a strict liability offence. The principle of strict liability has a long history in sports anti-doping measures, having been applied by pre-Code anti-doping rules and the International Olympic Committee Anti-Doping Code, the forerunner to the WADA Code. Strict liability is defined as liability incurred for causing damage or harm to life, limb, or property without the necessity of proving intent or negligence, meaning that an athlete can be found guilty of an ADRV even where there is no (proof of) intent (ADRV 2.1). Doping may therefore be unintended, and an athlete violation judged to have been committed, with a sanction likely (although not necessarily) imposed even if the offence is unintentional. For example, the consumption of food that unbeknown to the athlete, contains a banned substance- if tested and results include an adverse finding it is not a defence to claim ignorance. However, it may lessen the sanction imposed under some circumstances as specified in the Code Anti-Doping Rule Violations (ADRV).

The ADRV list describes a range of actions and omissions that are infractions of the code and carry sanctions. Together they characterise doping as defined by WADA. Generally, public perception of doping is that it involves the use of performance enhancing or otherwise prohibited substances or methods, understandable given the media coverage of cases involving high profile elite athletes and teams (See Kelner, 2018; Roan, 2019 for example).

However, misleading the doping control officers as to your whereabouts, or interfering with a blood or urine sample given to a doping control officer are also anti-doping rule violations that lead to sanctions. It is important to understand the heterogeneity of the actions and omissions that count as a rule violation, as they carry equal weight and also to illustrate the complexity of the rules and expectations upon athletes subject to doping controls.

5.6 Whereabouts

In the anti-doping context, 'Whereabouts' refers to

> 'information provided by a limited number of top elite athletes about their location to the International Sport Federation (IF) or National Anti-Doping Organization (NADO) that included them in their respective registered testing pool as part of these top elite athletes' anti-doping responsibilities' (WADA 2021).

WADA claims that out-of-competition doping controls, specifically no notice testing, are a powerful deterrent and means of detection of doping (WADA, 2019;2021). Knowing the whereabouts of eligible athletes in order to be able to test them without notice is a key part of that process. Whereabouts rules are part of the IL and are therefore mandatory for Anti-Doping Organizations that have adopted the World Anti-Doping Code (the document harmonizing anti-doping rules in all sports, WADA 2021).

As Bloodworth & McNamee (2017) point out, the whereabouts policy is contested. All athletes in a Registered Testing Pool must submit whereabouts information for one hour per day between the hours of 7am and 10pm to be available for testing controls without notice. The intrusive nature of such policy is widely discussed (Møller 2011, 2012) as is the fact that there are no international standards for the inclusion criteria of the registered testing pool (McNamee, 2012).

The levels of athlete defined in the Code are National, International, minors, Protected Persons, Recreational. Each group is defined by the NADO and IFs and as such there is no single standard for deciding membership of one group or another. Although only elite athletes selected to be in a registered testing pool (RTP) are subject to whereabouts, they are not the only athletes for whom out-of- competition testing is possible. Any athlete subject to doping controls may be randomly chosen for testing (WADA 2021a). WADA explicitly aims to harmonize doping controls and states that 'it is critical for purposes of harmonization that all Signatories base their decisions on the same list of anti-doping rule violations, the same

burdens of proof and impose the same Consequences for the same anti-doping rule violations. These rules must be the same whether a hearing takes place before an International Federation, at the national level or before the Court of Arbitration for Sport' (WADA 2021b: 12). The scope and severity of restriction and obligations on athletes governed by a sporting body (IF, NADO) and the lack of athlete representation on the relevant decision-making bodies, including the managing committees of WADA, has led to increased calls for representation. Due to the expectations upon them regarding doping control, and the dynamics of contractual and medical relationships, athletes are in a unique position compared to other 'workers' and their journey to gain representation and access power reflects this.

5.7 Stakeholders

5.7.1 Athletes

Athletes are the stakeholders primarily subject to and affected by doping and doping control. Noting that support personnel may also be found liable for ADRV, under seven of the eleven criteria set out in the Code (WADA, 2021), but are not automatically liable when an athlete they work with is convicted of a doping offence. The term 'athlete' might seem to imply a homogenous group with shared interests, however global sport means global cultural and political, social contexts as well as huge diversity across a range of protected characteristics; including but not limited to gender, ethnicity, language and the sport in which the athlete specialises. Athletes can also be characterised in terms of being the people who take part in sports and are therefore subject to the various controls, restrictions and other obligations that the current anti-doping regime mandates. This may be in opposition, or at least difference, to the interests of organisations and their officials. There are a number of shared interests between all stakeholders, for example the 'play true' slogan refers to the widely held wish for 'clean sport' and fair play that extends beyond athletes themselves. However financial and political interests also play a key role in sport at the elite and international levels, for example the revenues brought in from sponsorships, ticket sales and broadcasting rights as well as the politics of where events are held and state support for major competitions. Athletes subject to doping controls have long asserted that they are the largest and most burdened but least heard stakeholders (Athlete Committee, personal communication, 2020). The power and reach of WADA has continued to grow over the years and is not without critics, who question the effectiveness of current anti-doping approaches and the way in which WADA and associated

organisations operate (Hanstad & Loland 2009; Møller 2016).

The WADA athlete committee, was convened in 2005 and updated in 2019 with expanded purpose as a response to complaints that athletes were not being heard by WADA and other organisations making decisions that directly impact them. The athlete committee's stated purpose is 'to provide an athlete perspective to WADA Management, the WADA Executive Committee and Foundation Board on all relevant anti-doping matters, and to represent the views and rights of athletes as it relates to anti-doping' (WADA, 2019). The committee is currently advisory, without decisional power, however one of their medium to long term aims is to have athletes on the Executive Committee and Foundation Board. Intersectionality and fair representation of the diverse athlete communities is a key challenge acknowledged by the committee and working groups. See Chapter 7 for more detailed discussion of representation and engagement with athletes on policy around doping control and related research.
The introduction of the WADA Athletes' Anti-Doping Rights Act in 2020, developed in consultation with athletes, is an important step in the move to better hear and include athletes in decision and policymaking about doping control. It should be noted the Act does not confer legal rights and that the only legal rights for athletes in the anti-doping context are 'those rights that are set forth in the Code and International Standards regardless of how they are described in this Act. In case of conflicting interpretations, the provisions of the Code and International Standards shall prevail in all cases' (WADA, 2020). The Act is in two parts, setting out existing rights in Part 1, while Part 2 contains recommended athlete rights 'that do not exist universally within anti-doping and are not rights under the Code or International Standards' (WADA, 2020). Part 2 rights are those that athletes encourage ADOs to adopt and apply in order to 'further enhance the fight against doping, the integrity of the system, and athlete rights within that system' (WADA, 2020). As the Act and athlete committee have both only recently come into existence it remains to be seen how much impact they will have in addressing athlete concerns and protecting and promoting their interests. One area of particular interest here is (athlete) consent to testing and research use of samples and data, including the potential for third party access and biomedical research secondary to doping control uses and the ways in which the dynamic between athletes and anti-doping organisations and practices affects that consent. Examining the history and development of the anti-doping movement and the relationships between actors and with infrastructures can inform development of new processes and support best practice.

5.8 Conclusion

The chapter provided an overview of anti-doping development and the key actors and instruments in the current landscape to establish context for discussion of regulation and harmonization of the ethical governance of data and samples arising from doping control. It situates6y ADAMS within the ethical challenges associated with both the anti-doping movement in sport and multinational biobanking. The context of sport and doping is a complex and global one, spanning a wide range of disciplines and stakeholders, as well as international law and in particular the specialist Court of Arbitration for Sport. Doping control and associated activities entails the collection, storage and management of large quantities and types of data from numerous sources, including but not limited to Whereabouts, ABP and sample testing. An important, and wholly WADA owned, repository for anti-doping data is the ADAMS database. The challenges and opportunities specific to the potential research use of doping control and other associated data, such as held in WADA'S ADAMS database are most usefully understood in respect of doping control, situated in a wider societal context. The ADAMS repository content has significant potential value for research beyond anti-doping and the range of ethical considerations involved in doping-related and facilitating external non doping-related research access and secondary uses of ADAMS data are considered in the next chapter.

6 ADAMS

This chapter critically analyses the ethical challenges surrounding the secondary uses of anonymised data in the World Anti Doping Agency (WADA) Anti-Doping Administration & Management System (ADAMS) database. Secondary uses include anti-doping research, and a range of biomedical research areas, by third-party researchers. It examines athlete consent to primary research uses of samples and data arising from samples, collected for doping control and how the validity of that consent affects the development of an ethical process for potential secondary uses. It sets out challenges particular to gaining consent to research uses in the elite sport context and how consent to research may be conflated with consent to testing. There follows a discussion of the problem of consent in open-ended data-based research using data derived from samples originally collected for testing including ways in which the dynamic between athletes and WADA, as well as the setting in which consent is sought, may combine to prove coercive, or at least manipulative or constraining. I examine whether or not any manipulation or constraint is problematic and in what ways. Following on from analysing the ethical challenges, suggestion of ways in which WADA and any potential third party researchers accessing the data, might embed ethical practices to minimise the risk of harm as well as means to mitigate harms if they occur.

6.1 WADA

The World Anti Doping Agency (WADA) owns a database called ADAMS that holds records of elite athletes. Currently, WADA conducts anti-doping research using ADAMS data but does not allow third-party access to the data. WADA's main activities include (anti-doping) research, education and development of doping controls as well as funding external research activity. WADA also monitors and updates the World Anti-Doping Code (The Code WADA, 2021) with the aim of harmonizing anti-doping policies across all sports and countries. There are some exceptions to this such as the NFL, where athletes are employed as professional players, though such athletes would still be included if they were to compete in the Olympics or a similar 'amateur' competition. It is WADA's stated mission to 'lead a collaborative worldwide movement for doping-free sport' (WADA, 2019).

According to the terms of the Lausanne Declaration, the World Anti-Doping Agency (WADA) was established on November 10, 1999, in Lausanne to 'promote and coordinate

the fight against doping in sport internationally' (WADA, 2019). WADA was set up as a foundation under the initiative of the IOC with the support and participation of intergovernmental organizations, governments, public authorities, and other public and private bodies fighting doping in sport. The Agency consists of equal representatives from the Olympic Movement and public authorities. It has been suggested that this model leaves WADA susceptible to geopolitical influences and that they themselves act as a 'power' on the international stage (Ohl, Fincoeur & Schoch, 2021; Dyner). Sport and sporting events play an important role in international relationships in terms of finance and politics and there are aspects of the development of the anti-doping movement that reflect the global political contexts at the time. The history and values of the anti-doping movement were explored in more detail in Chapter 5.

WADA justifies the activities and restrictions of the anti-doping movement on the grounds of athlete health, public health and the spirit of sport (WADC, 2021; Ritchie, 2013). WADA recently moved health to the top of its list of rationales for current anti-doping activities. This has potential implications for the justification and management of research access to ADAMS data, as will be explored in Section 6.8. There is international backing for a public health justification of anti-doping measures: 'The European Court of Justice has accepted that combating doping is necessary to safeguard both athletes' health and the ethical values of sport. As such, the legitimate objective of combating doping necessarily impinges on certain freedoms ordinarily enjoyed by athletes under the Treaty (Case C-519/04 P)' (WADA, 2014). Additionally, Article 165(2) of the Lisbon Treaty provides that 'the Union's actions shall be aimed at "protecting the physical and moral integrity of sportsmen and women…", and that the Union must take into account the "specific nature of sport" and "its structure based on voluntary activity." (Treaty of Lisbon, 2007).

A case before the European Court of Human Rights (ECHR) case upheld the Whereabouts rule on the basis of public health (ECHR, Case C-519/04 P 2014). The challenge brought to the ECHR under Article 8 of the European Convention on Human Rights was dismissed on the grounds that the importance of the public authority (WADA, iNADOs) being able to test without notice and outside of competition outweighed the invasion of privacy of athletes. The judgement was based on the claim that doping harms athletes, and that athletes are held in regard by young people in particular and therefore there is a need to control doping, Whereabouts restrictions are a key part of the global anti-doping effort led by WADA. The ethics and efficacy of Whereabouts is debated in the sports policy literature, but a detailed

analysis is outside the scope of this work (See e.g. MacGregor et al, 2013; Waddington, 2010; Valkenburg, de Hon& van Hilvoorde, 2014) The global doping control effort is a complex, multi-faceted movement that involves research into for example prohibited substances, doping techniques, detection methods and how various substances and techniques affect athletes' bodies. WADA accredited laboratories carry out testing on samples obtained from eligible athletes. Some also conduct research in the range of areas mentioned. The validity of consent obtained from athletes has been questioned with regard to voluntariness and informedness (Kleiderman et al, 2019; Deveriendt et al 2019).

The ISPPPI and ISL explicitly state that data and samples taken with consent for testing and research can only be used for anti-doping research and requires that anti-doping research shall comply with internationally- recognized ethical practices (WADA 2021).

According to Article 19 of the WADC, anti-doping research may include, for example, sociological, behavioural, juridical and ethical studies in addition to medical, analytical and physiological investigation. Studies on devising and evaluating the efficacy of scientifically-based physiological and psychological training programs that are consistent with the principles of the Code and respectful of the integrity of the human subjects[29], as well as studies on the use of emerging substances or methods resulting from scientific developments should be conducted.

Currently, the International Standard on Testing and investigations (ISTI) requires WADA accredited labs to spend a certain proportion of their budget on 'research that supports doping control' (WADA, 2021). This may motivate labs to focus on research that affirms current approaches to doping controls, rather than challenging them. That is problematic because doping is constantly evolving, for example the ongoing development of new drugs and new techniques which are disseminated at speed and for profit. Therefore, what counts as anti-doping (research) also needs to adapt. This may be problematic for a broad consent that includes 'anti-doping research' as it does not account for shifts over time or between

[29] Some scholars equate integrity with actions that demonstrate high moral and ethical standards, and others call it a morally neutral term equating it with the law of gravity (Monga, 2015). In research ethics it is used in the former sense but also refers to preserving the whole i.e., not compromising the integrity of data in terms of standards and completeness. Integrity in the ethical sense is often the focus of guidance at institutions e.g. 'research integrity' policies but can become a catch-all word that is in fact about compliance with rules. Moral integrity of researchers and research should be a priority for governance and research design.

locations. See Chapter 4 for further exploration of broad consent and its application in the biobanking context.

6.2 Research and Education

WADA carries out research on a range of doping related topics for example the development detection methods and predictive work on 'emerging doping threats'. Research and related activities are overseen by WADA's Health, Medical and Research Committee with expert groups on the Prohibited List, Therapeutic Use Exemptions (TUE), Laboratory accreditation, and Gene Doping tasked with leading WADA's research in their respective areas. These groups report to the Health, Medical and Research Committee. WADA funds external research via a grants programme with areas of scientific interest published per year. Emerging and urgent topics may also be funded.

The Social Science Research Expert Advisory Group exists to provide expert advice, recommendations and guidance to the WADA Education Committee and WADA Education Department on all sport doping related social science research. Education has long been a part of the anti-doping strategy for WADA and in the 2021 Code the first IS for Education was introduced. The introduction of this standard may be seen as an indication of the increased prioritisation of education as a key aspect of prevention and working towards culture change. Education is also closely linked with the elevation of public health as both a justification for and an approach to anti-doping, and provides a relatively low cost way to reach beyond elite sports and increase engagement at all levels. Research and education inform each other and anti- doping activity, and are increasingly prioritised in successive updates to the Code.

The Anti-Doping Administration and Management System (ADAMS) is the WADA owned repository for doping control data and currently ADAMS data is used for doping control and for doping-related research however it has potential application in wider biomedical research. ADAMS was created by WADA to 'facilitate the sharing of information amongst relevant organizations and promotes efficiency, transparency and effectiveness in all anti-doping activities'. In practical terms, ADAMS enables the coordination and planning of testing, management of results including submission of test results from WADA accredited laboratories and TUE, Whereabouts information. Athletes who join a registered testing pool

(RTP) are given education on processes, rights and responsibilities by the relevant sporting body, usually their NADO or IF.

The aims of WADA's Education programme and dedicated units within NADOs and others include prevention (of doping and cheating in sport), outreach (to athletes and sporting organisations at all levels)- which parallels with public health and global health work-. awareness of doping and controls outside of elite sports including the public health rationale for anti-doping activity and the potential health-related harms of PEDs and substances of abuse. Education is also part of culture building in minor and youth sports, in tandem with attempts at culture change in adult sports, which is much more difficult. 'Play true' is the WADA motto, which appeals to the ideals of sport beyond health concerns or rules. The recently launched Anti-Doping Education and Learning platform (ADEL) contains education modules in multiple languages for a range of topics including the Code, Olympics, Whereabouts amongst others. A research module developed in partnership with athletes, WADA and ADO education personnel and researchers, could be added to this suite. Uptake would need to be supported with tailored engagement and potentially connection to e.g., athlete access to ADAMS.

The International Standard for Education (ISE), first introduced in the 2021 Code, affirms the key role for education in anti-doping programmes and in WADA's strategy planning. The ISE sets out WADA's role regarding education and the requirements that Code Signatories need to meet. WADA's role in education is stated as: '1. Regulate anti-doping policy as it relates to education and 2. Enable the development of ADO education programs' (ISE, WADA 2021). Code signatories, sporting bodies and governments are responsible for education. WADA's Education Department also leads the 'educational initiatives that support the capability development of ADO practitioners' (WADA, 2021). This means that the education section of WADA has responsibility for educating athletes and for training regarding anti-doping requirements and responsibilities. Education is a core component of any anti-doping program and the introduction to the 2021 Code includes education in the prevention of intentional or unintentional doping, along with deterrence, detection, enforcement and the rule of law.

6.3 ADAMS database

The Anti-Doping Administration & Management System (ADAMS) database, housed at WADA global headquarters in Montreal, Canada contains approximately 264,000 records of elite athletes from around the globe (as at 2014, no more recent figures available). 'ADAMS is a clearinghouse where all data can be stored, in particular laboratory results, Therapeutic Use Exemptions (TUEs) and information on Anti-Doping Rule Violations (ADRVs)' (WADA, 2019). It facilitates the sharing of information amongst relevant organizations and promotes efficiency, transparency and effectiveness in all anti-doping activities. ADAMS has been implemented and is used by approximately 60 International Sport Federations (IFs), more than 40 National Anti-Doping Organizations (NADOs) and by all WADA accredited laboratories. Users include 3,000 ADO staff from National and Regional Anti-Doping Organizations, IFs, Major Event Organizations (MEO), and delegated third parties, such as the International Testing Agency (ITA) as well as approximately 160 personnel from WADA-accredited laboratories; and 150 experts from Athlete Biological Passport Units. All of these user types have limited access that specific to their need.

The largest group of stakeholders are the approximately 30,000 athletes whose data are contained in ADAMS (WADA, 2021). The findings indicate that more and more individuals and organizations are entering testing data directly into ADAMS (from 56% in 2015 to 87% in 2016 and 91% of testing data was entered in 2017-most recent available figures). Athletes had been able to access some of their data in real-time, however the WADA Executive Committee recently approved the removal of that immediate access to their Athlete Biological Passport (ABP) haematological data in the ADAMS. This decision was based on evidence from the 'Operation Aderlass' investigation that revealed that some athletes were able to monitor their ABP data in ADAMS. This meant that, with the help of support personnel, they were able to adapt their strategic doping and avoid detection. Under the International Standard for the Protection of Privacy and Personal Information (ISPPPI), as well as privacy and data protection laws, Athletes have the right to access their personal information but 'this right does not require that the data be directly or immediately accessible via ADAMS'(ISPPPI, WADA 2021). Following this change, athletes will continue to be able to request a copy of their ABP blood data from the relevant ADO (WADA, 2021). This example illustrates the particular kinds of challenges that ADAMS offers, as athletes are obligated to provide information and have rights of access, but can use that information in

ways that subvert the core premise of ADAMS as an anti-doping resource i.e. to alter their behaviour in order to continue doping. This is not the only aspect of ADAMS that requires careful consideration concerning potential research use, a range of which are discussed throughout this chapter, but it serves as an introduction to the particular ethical and governance challenges associated with this non-voluntary, non-medical bio-data bank.

A number of large sporting event organisers also use the system to manage in-competition testing programs at events. Between all the users to date approximately 100,000 athlete profiles have been entered. Athletes may have multiple profiles from different stages of their career and locations, affecting the overall number of profiles and records, though work is being done to reduce this duplication. The use of ADAMS has been mandatory for anti-doping organizations (ADOs) since 2016. According to WADA, ADAMS allows Anti-Doping Organisations (ADOs) to 'coordinate their anti-doping activities and to fulfil their responsibilities under the WADC in a highly secure, cost and time-effective way' (WADA, 2020)

Results from samples analysed by WADA accredited laboratories are coded and anonymized before being sent to ADAMS. Data gathered in ADAMS is not taken for diagnostic or other purposes considered to be research but to identify levels of steroids, hormones and for the purpose of uncovering other ADRVs such as banned substances. As stated on their website, WADA is 'committed to increasing the volume of research dedicated to developing new and improved detection methods for prohibited substances and methods' (WADA, 2021). This historically refers to social science and sample-based research, but can be reasonably assumed to include exploration of existing data in ADAMS, all of which is anonymized.

Recital 26 of the GDPR defines anonymous information, as '…information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable' (GDPR, 2016). The ADO responsible for results management, the IF and WADA are the only parties that have access to the results and they do not have access to the anonymization codes or keys. There is currently no single standard for anonymization of data sent from testing laboratories to ADAMS, which might lead to different levels of identification risk across different data sets, or between countries of origin. Standardisation of anonymisation procedures is being investigated by WADA (O.Rabin, personal communication, 2018). Whilst there is ongoing work to improve practices, there is also some concern that laboratories do not challenge

practices they may consider to be sub-optimal due to the hierarchical and financial nature of their relationship with WADA (O.Rabin, personal communication 2018; Devreiendt et al, 2019; WADA 2021).

From 2018 onwards data can be stored within ADAMS for a minimum of eight years, to reflect the time during which an Anti-Doping Rule Violation (ADRV) can be acted upon in the World Anti-Doping Code (WADC). This deadline is altered when relevant (for example 18 months is the maximum retention for whereabouts, because failure to provide accurate whereabouts information within an 18-month period can lead to the opening of a disciplinary proceeding by the ADO with jurisdiction over the athlete). This means that some whereabouts information will have already been automatically deleted by ADAMS prior to being accessed by researchers. Researchers may need to consider the ways in which deleting data may have altered the aggregated datasets before attempting to mine the data at scale. There are a number of imputation techniques used by data scientists to attempt to compensate for missing data (Bertsimas et al, 2018). Bias may be introduced, or existing bias exacerbated by loss of data depending on what types and what amount of data is altered or deleted as a proportion of the whole dataset(s). Bias may also be introduced when seeking consent over multiple interactions, as those who refuse and those who consent to a given type of research may be materially different (Ioannidis, 2013; Rothstein et al, 2013). However, there would need to be a significant proportion of refusals and withdrawals for there to be a statistical impact, especially given that it is not possible to withdraw data from datasets that have already been aggregated or analysis already conducted. This speaks, once again, to the limitations of the right to withdraw in the context of anonymised datasets and the importance of clear communication about this from the outset.

Athlete data in ADAMS that are not derived from samples include identity, date of birth, gender and in which sports an athlete competes including their level of competition as set out by their NADO or IF. Whereabouts information including travel, periods at home and away and ‘information about your mobile device’s location’ is retained and if an athlete has a TUE in place then this is also recorded in ADAMS.

Doping control data including testing, sample collection and results, hearings regarding potential violations and data from the Athlete Biological Passport (ABP) are held in ADAMS. The anonymised data may be considered to be personal data depending on the jurisdiction in which an athlete is resident. GDPR defines ‘personal data’ as follows: ‘Any

information related to a natural (living) person or "data subject," that can be used to directly or indirectly identify the person' (GDPR, 2016) (See Section 2.3 for further detail on data types and the GDPR). Examples include: a name, a photo, an email address, bank details, posts on social networking websites, medical information, computer IP address and for athletes: Whereabouts, Athlete Biological Passport information.

There is no one definition of personal data in ADAMS and protections may differ across countries. For jurisdictions covered by the GDPR, and for data originated in those jurisdictions or from EU citizens, but processed outside of them, anonymised data are not considered to be personal data and therefore are not included in the GDPR's remit. This is just one example of legislation that applies only to personal data. The data contained in ADAMS are highly sensitive, but as they are anonymised they are not considered to be personal for the purposes of the GDPR and other relevant legislation. The Athlete Biological Passport (ABP) is a significant source of health-related data in ADAMS that plays a key role in the surveillance of athletes over time.

The Athlete Biological Passport (ABP) is designed to 'monitor selected biological variables over time that indirectly reveal the effects of doping rather than attempting to detect the doping substance or method itself' (WADA, 2021). This is achieved by collecting athletes' haematological variables and establishing steroid profiles via urine test analysis in WADA accredited laboratories. The ABP aims to provide a baseline for an individual in order than testing may show changes in that individual's levels, rather than differences between individuals that may well be normal for those individuals as hormones levels are on a spectrum across the population both between and within a given gender. The ABP information contained in ADAMS can therefore be considered to be highly sensitive and having the potential to cause harms. The data are permanently anonymized and de-linked in order to preserve athlete's privacy however this does not solve all the potential challenges to ethical secondary research on the data.

The datasets contained in ADAMS are of enormous cultural, geographic and genetic diversity, hence the potentially significant value for multiple types of secondary research. The potential research value of which will likely only increase over time if/when more genomic data are added, due to the widening of research scope that would accompany such additions and the replicable nature of genetic material and data. WADA currently have no plans to introduce genome wide association sequencing (GWAS) into ADAMS, but there are

data derived from tissue from which genetic and epigenetic and broader health-related information can be deducted. Additionally, there is a large amount of data on the internet about many athletes and this can also be utilised to infer information that is not directly the result of testing or the other data types in ADAMS. An example of this is determining biological sex or vaccine-status through ADAMS data, perhaps in combination with social media and health data. The database is so diverse in terms of genotype and phenotype as well as being longitudinal because ADAMS has been in use in various iterations for over 10 years. Athletes from across the globe have contributed a range of types of data from samples of urine and blood, as well as whereabouts information and other data sets over that period. The scale and range of the data is increased in part because there are multiple entries per data type per athlete, and often over the length of an athlete's career. This means that ADAMS is a unique biobank resource with a significant collection of sample-derived and other types of data that have the potential to be used for anti-doping and for biomedical research. It also means that there will be data in ADAMS obtained from athletes who have since retired, may have died or have disengaged from the activity that led to their information being in ADAMS. For this subset of people there is a reduced or zero benefit to them from anti-doping research and they will be difficult to contact if consent were to be sought for broader secondary uses. They might choose to allow research uses of their data in order to contribute to the sporting community, or for some other altruistic or pro-social reason, however the inability to ask is as problematic here as it is for those who object. One way to reduce the challenges would be to set a cut-off date before which consent is not required, but it is assumed that the contributors of that data would be willing. It should be noted that it is not just the age of the data, but the access to information about intended uses and length of retention for example may have been less robust than it is today. 'No Sample may be used for research without the Athlete's written consent. Samples used for purposes other than Article 6.2 shall have any means of identification removed such that they cannot be traced back to a particular Athlete' (Art. 6 WADC 2019:44).

Athletes are able to see which organizations have ability to access their ADAMS data and are informed of changes via the access portal. All parties accessing ADAMS data must adhere to the International Standard for the Protection of Privacy and Personal Information (https://www.wada-ama.org/en/adams-privacy-policy) In order to accommodate the differences in data protection regulations in different jurisdictions all transfers of data must

also meet the WADA International Standard. WADA and associated ADOs have the right to process data on the basis of legitimate interests as set out in the Code:

> 'you may have a right to object to the processing of your data, although in that event, and as noted above, it still may be necessary for your Custodian Organization and WADA to continue to process (including retain) certain parts of your data to fulfil obligations and responsibilities arising under the Code' (WADC, 2021).

Without specified parameters or clarification of obligations and responsibilities for the Custodian Organization, WADA or the athlete, this looks like blanket consent, which may not be a problem in and of itself. Article 21 WADC refers to processing for anti-doping activity rather than research, but there is no specific exclusion of research use and it is therefore feasible that research could be counted under this very broad reading of 'processing'. This may be especially the case given that the definition of anti-doping research appears to be flexible and may change over time, as do perceptions of research and of data use more generally. For example, what was considered to count as a 'health record' a decade ago will not fully encapsulate all the items that a health record is able to include now and therefore even where consent has been provided, shifts in technology and social meaning may lead to breaches of consent terms.

Information for athletes includes the note that 'preventing the processing, including disclosure, of your data may prevent you, your Custodian Organization, WADA or other ADOs from complying with the Code and relevant WADA International Standards, which could have consequences for you, such as an anti-doping rule violation, under the Code' (WADA, 2021). This would appear to mean that not only is consent not required, which is the case for many other contexts and may not in itself be problematic, but that refusal has potentially serious consequences for the athlete's career and associated wellbeing. The consent refers to processing of data and not research specifically but the phrasing is so broad as to potentially include such uses.

6.4 Voluntariness and coercion

There appears not to be an explicit threat in the WADC wording regarding processing and refusal to process data. It is possible that athletes might perceive there to be an implicit threat given wording such as '…consequences for you, such as an anti-doping rule violation, under

the Code' (WADC, 2021). Certainly, there appear to be potentially serious consequences for athletes' ability to participate in their sport following any refusal to allow data processing.

If the way in which athletes are asked for permission to process data, to use their samples and data for research is not coercion, it may still be manipulative. Whether or not this is an ethical problem beyond those constraints on choice that occur in any other societal context will be explored here. There is a significant literature on coercion taking in political and moral philosophy and psychology. This is not an attempt to comprehensively review that literature, but to understand how the discussion of data use between athletes and WADA, including seeking consent, may or may not be coercive or manipulative. In order to consider these questions, first I outline the conditions for consent to research in elite sport, in particular voluntariness, and challenges to it that arise in the context of anti-doping and examine the possibility of a duty to participate

Autonomy is a condition, meaning that a person may have capacity and therefore the accompanying right to self-govern but find themselves in conditions that render autonomous decision making very difficult, or even impossible. In-competition testing for doping may meet this threshold for impairing decisional autonomy for some athletes. The combination of focus on preparation to compete, internal and external pressure to do well and the high stakes nature of elite competition create a uniquely pressured environment in which to ask for consent to a future act with potentially significant consequences. The consent to testing is questionable in terms of voluntariness for a range of reasons explored by (McNamee, 2012; Kleiderman et al, 2019) but detailed interrogation of the competitive environment is outside of the scope of this discussion. The consent to research uses is a tick-box on the WADA consent-to-testing form. This sets up the potential for conflation of testing and research in the athlete's mind, in particular because of the serious adverse consequences of a refusal to testing. When this is considered in light of the requirement to agree to processing of data, it seems even less likely voluntary consent to research uses is possible under those circumstances. A seemingly simple remedy to the problem would be to separate the two requests for consent. Although this may have logistical and administrative demands, they are unlikely to be sufficient to negate the ethical benefits. Thus far the discussion has assumed that consent should be a free and individual choice that is based in the norms of consent e.g. autonomy-protection but also in what the consent-giver believes to be the correct choice, respecting their will and decisional capacity. The decision not to take part has thus far received no particular moral attention and the decision to contribute perhaps being lauded or

thanked. It may be that the individual decision is in fact located in an obligation to participate and if that is the case then non-participation takes on a more significant weight. The potential obligation to take part in research (where reasonably able) (Harris, 2005) remains controversial and next we briefly explore some of the key aspects.

Potential grounds to support the obligation to participate include: beneficence; fairness; and societal duty to support the public good. 'Beneficence, or more specifically the 'rule of rescue', demands that citizens participate in research where doing so results in minimal personal harm and offers the potential to save future lives or prevent serious suffering' (Ballantyne & Schaeffer, 2018). Beneficence here refers to the bioethical principle underlying the duty to act in the best interests of others as well as ourselves. Beneficence implies action of "kindness, mercy, or charity" toward others. In the technical language of ethics, beneficence is to be treated as prima facie or potentially limited in nature (Beauchamp & Childress, 2013). Beneficence coexists with autonomy and may sometimes be in tension with it, but in general they should be given equal weight (Gillon, 1994; Beauchamp & Childress, 2013)[30]. Fairness may demand that we participate in research because we have benefited substantially from the health knowledge derived from previous subjects. To do otherwise might be to free-ride on the sacrifices of others. Finally, health knowledge is a public good and citizens' duty to preserve this public good entails volunteering for research (Harris, 2005).

If a duty to participate exists then we might think that consent to secondary uses is not required. Such a duty does not make research participation compulsory particularly not invasive clinical research. However secondary uses of existing data, for example health records or athlete information from ADAMS, which is generally considered to be minimal risk, might be justifiable. The literature on the duty to participate and its limits is largely concerned with identifiable data, but here we apply the questions and principles to anonymised data, such as that in ADAMS. The anonymisation of data is not a catch-all solution to the ethical challenges of using person-derived information for research. Yes, anonymisation removes or at least significantly reduces the risk to privacy but it does not answer the challenges to autonomy that using data without express permission creates. The duty to participate is a move away from the prioritisation of individual autonomy, to a public goods, solidarity-based model for justifying research participation and uses of data. With

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regard to anti-doping research, a duty to participate based in solidarity seems to fit with WADA's core messages on community and clean sport. This may be less the case for wider biomedical uses where we consider the 'athlete' and their place as a member of the sporting world. If we set aside 'athlete' and consider the human, then it would seem that almost the reverse case is true: the ordinary person may not feel a duty to participate in research benefitting athletes but may want to support research into common diseases. Of course, it is normally not possible to split apart the identities that a person inhabits, but it is helpful to illuminate the multi-faceted nature of the self and therefore the motivations and priorities. This type of exercise may also be helpful in determining what kinds of limits on freedom and voluntariness a person may experience and the ways in which different persons (athletes) may be influenced, or not, by similar circumstances.

According to Olsaretti, the limiting of an agent's rights and freedoms by another does not necessarily mean their choices are involuntary: 'Freedom refers to the choices we face and voluntariness to the choices we make' (2014:59). Voluntary action can be described as 'acting freely' based on information received i.e. the nature of the choices available affects how free we are to decide between them. This speaks directly to voluntariness of choice or consent in the context of doping control, particularly but not exclusively so for in-competition testing.

Voluntary consent must be given in the absence of controlling influences, or at least not be significantly affected by those influences where they are present (Nelson et al, 2011). Most interactions take place in proximity to some influences; it is the 'controlling' aspect that is key. The degree of that control and therefore the strength of influence is one property that determines the type of persuasion. There follows a brief consideration of two kinds of persuasion that are proximal to coercion: nudge and manipulation.

Nudge is a theory from behavioural economics, developed by Sunstein & Thaler, that can be most simply described as a form of paternalistic persuasion that is carried out without limiting available choices: A nudge is a 'small feature of the environment that attracts attention' (and suggests a course of action). The most famous example is the picture of the fly in the urinal, which was shown to reduce spillage by approximately 80% (Sunstein & Thaler, 2008) Nudge can work in conjunction with stronger requirements, such as the consequence of not competing if testing is refused.

In ‘nudging’, the choice architect is the person or entity that creates the environmental feature or ‘nudge’ doing the work. In this case the architect is WADA, because it designed the athlete consent form to ask for consent to research on the same form as consent to testing. Importantly, nudge does not limit choice but presents choices in such a way as to ‘nudge’ a person towards one or the other. If we take the example of the consent then the athlete is nudged to consent to research by it being in proximity to the consent to testing request, which is a requirement if an athlete wishes to compete. There is no clearly marked line between nudge and other, stronger, forms of manipulation but it can be considered in terms of the cost of opting out. If it is costly i.e., difficult and or leads to an adverse consequence then the cost of opting out potentially shifts the ‘nudge’ to become a mandate, a mandate being defined as something that compels through the cost of non-compliance (Sunstein & Thaler, 2008). In the case of consent to research from athletes, the consequence (being disallowed from competition) arises from refusal of consent to testing, not directly from refusal to consent to research. The placement of the two consent requests therefore cannot be a ‘nudge’ but it may yet be manipulation.

Manipulation is a commonly used word and there are many situations and relationships in everyday life that might be justifiably described as manipulative. It is not an essentially pejorative term, but depends on the intention behind and context surrounding the manipulative situation or act. Unlike coercion, there is no threat required in order for something to be described as manipulative. There is debate as to whether intention is required, or whether it is possible to be manipulated unintentionally but this does not apply to the conditions for consent to doping controls or to associated research.

Noggle (1996) notes the assumption that manipulation must involve deception, but this is not universally true. It is possible to manipulate someone into choosing the path preferred by the manipulating party without deception. If we take it that deceptive manipulation is morally wrong, because of the deception, then we need to ask about the moral status of non-deceptive manipulation (Noggle, 1996): Here manipulation is understood as leading a person away from attaining their own goals or ideal and towards the one that the manipulating party wants for them. If the intent is to ‘do good’ by leading a person towards something that is for example healthier, or will benefit others then we might think it more acceptable than if the intent is solely to benefit the manipulator. This way of thinking about manipulation rests on the intent (and consequences arising from the actions of) of the manipulating party. Manipulation may be direct or indirect. An indirect approach could involve providing

irrelevant information, or too much of it, thereby hiding the parts relevant to the agent making the choice. In the athlete consent to research context this misdirection might be achieved by having the consent form cover both research and testing, where the information and educational focus prior to the consent interaction has been overwhelmingly on testing and associated requirements and sanctions. The type of manipulation most applicable to the WADA context might better be described as manoeuvring. Manoeuvring a person into limited choice differs from nudging, because of the choice limiting, and therefore moves closer to a form of strong paternalism[31] (Sunstein & Thaler, Noggle, 1996). We might add the condition that it benefits the party doing the manoeuvring that the subject (of manoeuvring) makes a choice from the limited range made available, but the result will not necessarily to the detriment of the subject. I may manoeuvre a person into choices that benefit us both. Whether or not WADA manipulates athletes into agreeing to research uses might be determined by the intention behind actions which would be difficult to prove and may cause harm if wrongly stated. Therefore, this is not a claim that WADA or agents acting on its behalf *is* manipulating but an examination of whether that is a possibility and what may follow from that either being true, or not.

If there is manipulation, but not coercion by threat, or exploitation, then consent may be less impacted. Simply divorcing the two kinds of consent request would go some way to avoid having to attempt such distinction and it seems more practical and ethical to reduce the

[31] Paternalism exists on a spectrum from weak to strong and can be broadly defined as the restriction of choice or positive action-taking on behalf of a person, in their best interests, as decided by someone other than themselves. Moral paternalism may act in the interests of a person or society but is rooted in ideas of good and bad, for example, banning certain acts even if they cause no harm beyond the (autonomous) person who might take them. Here we are concerned with those who would ordinarily be deemed capable of autonomous decision-making, as this reflects the athlete population that is the primary interest group with respect to allowing research access to ADAMS data.
As Begon (2016) observes, even those who are anti-paternalist (e.g., Feinberg) tend not to argue that paternalism is 'prima facie impermissible'. Instead, most debate centres on how paternalism should be defined, and the challenges and potential wrongs that may occur as a result of a paternalistic approach to e.g., healthcare choices, research participation. We should consider whether paternalism should be understood as 'interference with our liberty for our own good, or only as restriction of our voluntary or autonomous acts' (Begon, 2016: 355).
If paternalism cannot be satisfactorily defined by the restriction(s) imposed on the subject it can perhaps instead be defined by reference to 'the distrust of another's ability to choose well for themselves and an assumption that they can choose better' (Begon, 2016:355). This may seem like a somewhat insulting reason, however, there may be times when agents do not reason well and therefore cannot fully realise their own interests, potentially justifying (limited) paternalistic interference. If the threat to autonomy is a key objection to strong paternalism then weak paternalism may be a more acceptable alternative. An example of weak paternalistic action is health warnings about certain foods, alcohol, justified on the grounds of harm prevention.

opportunity for coercive or otherwise manipulatory behaviours than to discern the proper term and then attempt to mitigate.

If context and the features of an offer or choice affect where it sits on the spectrum of voluntariness- from completely free to no other viable option- then we should think carefully about whether and how the non-medical, nature of anti-doping research might affect the coercion/manipulation of the offer. There is likely to be no direct benefit from research contribution to the athlete, but there is a direct benefit from taking part in doping controls due to the health considerations and professional risks from ADRVs. Some indirect benefit from research into anti-doping may be seen by individuals but also in their sporting community. It is not sufficient to consider whether or not an individual is making an autonomous, voluntary choice in isolation but allowance should be made for the role of altruism and communitarian thinking in that decision. This is not instead of individual rights and protections but to expand the ways in which we understand why and how people make the decision to contribute to research. The opportunity to abuse such thinking can be reduced by combining transparency about processes, including those relating to governance, with good quality governance and iterative stakeholder and public involvement as appropriate. Uncovering and interrogating the potential sources of influence, pressure, manipulation and possibly coercion is a vital part of working towards constructive relationships that facilitate valuable research without exploitation. Exploitation is understood here in the pejorative sense, to mean treating someone unfairly by exploiting a vulnerability or need, in order to benefit from their work or taking advantage of a situation to gain unfair advantage over others for one's own benefit (Feinberg, 1990). A more detailed consideration of coercion, as the strongest of these terms, and with most obvious potential for harm, follows.

Coercion refers to the techniques employed by coercer and the reasons why a coercee might do/not do something because of the coercive actions of another. We ought to differentiate justifiable coercion at the state level and that at the individual level. The latter can be seen as a wrong or harm in itself, in addition to the consequences it leads to. Coercion may also be a wrong without harm, i.e. where there are no adverse consequences (Feinberg, 1984).

Coercion is more than disapproval or manipulation: 'the ability to make such a threat credibly requires more than a simple intention and ability to execute the threat, but rather a whole system that effectively removes decision from the process…' (Stanford Encyclopaedia of Philosophy, 2019). This describes a system wherein it is not an individual decision or action that carries the threat but the whole set up: say yes to testing in-competition or do not

compete; comply with restrictions on movement, for example. The retaliatory action open to the coercee (athlete) is ineffective at best and at worst self-damaging: to choose not to compete may lead them to lose prestige, sponsorships, negatively impact career and even identity.

For Feinberg, coercion requires a credible threat i.e. the threat of a consequence that is worse for the agent making the choice than to carry out whatever it is they are being asked to do. If there is a credible threat, but the agent chooses to suffer the consequence rather than carry out the action then that is not coercion but pressure. For an interaction or situation to be coercive, the cost of not carrying out the action must be greater than the cost of doing it. Choices need not be impossible, but choosing not to act must be too expensive (when compared to acting), in order to force the action that the coercer intends to happen (Feinberg, 1984; Olsaretti, 1998). Here the discussion of coercion and associated concepts is limited to adults with capacity to make autonomous decisions. Decision making, and consent in particular, require clarity of information and governance of the activity being considered. There follows a brief outline of the challenges that arise in doping control, including operationalization of the Right to Withdraw (Section 6.5).

Doping control samples may be used by WADA accredited labs for anti-doping research after the expiry of the compulsory holding period for doping control. Clarity regarding what counts as research activity is needed. Differences between research and quality assurance are not well delineated. That matters because the latter does not usually require ethics review, therefore labelling activity as assurance may circumvent controls that exist to ensure quality and prevent abuses. Also, there is a lack of consistency or standardization of consent and interpretation of the relevant IS between accredited laboratories and local regulation may contradict what is set out by WADA. Devriendt et al (2019) propose centralisation of the consent form in the ADAMS database in order to facilitate both increased information provision and the right to withdraw. Provided that this also separates the location and timing of research consent from consent to testing, adding the form to ADAMS would seem a relatively straightforward and logical choice that would support, though not solve, the provision of valid consent from athletes.

The International Standard for Laboratories (ISL) states that samples with consent to research may be used for anti-doping research, whereas samples without research consent may only be

used for QA. As Devreiendt et al point out, the range of what could be called QA is both broad and not clearly defined. It also potentially overlaps the boundary with activities that could reasonably be called research. Herein lies a challenge for the ethical processing of those samples that have been given without consent to research. WADA and other stakeholders therefore need to further develop appropriate governance for the research uses and retention of doping control samples. The potential research use of data derived from these samples poses similar questions, the difference being that it would be secondary or re-use, coming after the primary research use of the samples themselves. There are risks associated with secondary research activity at group as well as individual level, and the Right to Withdraw remains a key aspect of protections for participants, discussed further below.

The types of harms discussed so far do not exhaust the possible negative effects of biobank research. Apart from harming participants, as mentioned above, one may wrong them by storing or using their samples. The continued retention of samples from indigenous peoples, or from those from whom permission was never sought, is an example of this kind of wronging, a well-known example of which is the Havasupai tribe's experience of their genetic data being used for purposes beyond those stated and that retention and uses violated tribal norms even though no harms to persons (Mello & Wolf, 2010; Garrison, 2013). Simply retaining materials may cause distress and disrespect cultural norms, around burial for example. In other words, one may illegitimately treat an individual even if they are not exposed to any risk of physical, psychological, social or economic harm. This a form of 'moral harm' (Kumar, 2003; Eriksson and Helgesson, 2005). It seems clear that this category of wrongs is relevant to the ethics of biobank research. It is also one of the motivations for the embedding of the 'right to withdraw' in research ethics, alongside reasons of privacy and autonomy.

6.5 The right to withdraw (RTW)

The right to withdraw is seen as fundamental to the ethical conduct of research by virtue of being integral to valid informed consent (Holm 2011; Schaeffer & Wertheimer, 2010; Melham et al, 2014). The Right to withdraw is predicated on the protection of individual autonomy and the idea that being able to withdraw from research indicates whether (choosing to) do it is voluntary. When thinking about the right to withdraw we must consider what it is made up of – firstly in order for a right to withdraw to be more than nominal, those who hold he right must be aware of it. This means being aware that they are part of an endeavour from which withdrawal is allowed in principle, *and* that withdrawal is in fact possible. The

Nuremberg Code sets out five components of the right to withdraw: It should be Absolute, Unconditional, Immediate, Complete and Inalienable. Biobanks and data-based research presents several challenges to these components in practice, for example the immediate right to withdraw may not be as necessary for biobank and data-based study as it is in clinical research, because no there is no significant threat to bodily integrity from research on stored samples and immediate withdrawal may threaten future autonomous choice (to participate). By withdrawing and destroying samples, donors or participants cannot take part in future research even where they change their mind. There is a potential for loss not only of current and planned research, but the unknown future research potential. This has a bigger potential impact than one person withdrawing from 'traditional' research where a sample and associated data are not linked or reused (Thompson & McNamee, 2017).

It is not necessarily the case that immediate withdrawal should equal complete. They should be considered separately, as there may be cases where immediate withdrawal is required but it is not possible for that withdrawal to be complete, for example where data have been anonymized and aggregated and therefore the link between the data and individual identifiers has been permanently removed. It may be possible to have a 'cooling-off period' whereby a contributor may withdraw from research immediately, but samples are not immediately destroyed. If samples and/or data can be kept sealed for a period (then destroyed or reopened as decided by the appropriate body) it is effectively as private as destruction, though reversible and theoretically at greater risk for re-identification just by existing compared to having been destroyed. It is vital to ensure donors know about all withdrawal options at sign up (Holm & Ploug, 2017; Thompson & McNamee, 2017). The RTW is fundamental to valid ongoing consent to research because without it consent becomes a onetime interaction, with the presumption that a person will not change their mind. Given that some athletes will have had data entered into ADAMS over a number of years, and in some cases there may be no consent in place, it seems reasonable to expect to make efforts to contact all those who would have data in ADAMS prior to allowing third party access. If consent is required, then efforts at contacting should be made. If it is decided that consent is not required then contact to offer information should still be made.

The right to withdraw is not absolute. In the case of anonymized data, such as in ADAMS, it is very limited as data cannot be linked back to the person from whose sample it was derived. If it is not possible to identify a participant then it follows that it is not possible for them to withdraw their data from research once it has been aggregated anonymized. This is not

necessarily problematic if it has been clearly outlined and the consequences understood by the participant at the outset. However currently that would not seem to be the case for athletes in ADAMS.

Where valid specific informed consent processes are in place, athletes or other research contributors should been aware of their involvement and as much detail regarding uses of their information as it is possible to provide. Where research processing of data is part of a broader permission to process data, awareness may be lower than for a solely research processing. Anecdotally, athletes are not very aware of research uses and show low levels of interest or engagement with processes that are not directly linked to their obligations under anti-doping regulation. For other forms of consent, knowing that one is part of a research project may be implied by having given consent, but in circumstances where signatories are not well informed about the uses of their materials or data the knowledge is questionable and therefore the validity of their informed consent is too.

Athletes whose doping related data are stored in ADAMS may not be aware of the broad purposes and scale of proposed research uses. They may not comprehend what consenting to research use means with regard to potential risks. As discussed, consent in these groups is often sought at times of focus and pressure, for example during a competition, and the level of detail given on the consent form and in the WADA information about research (See Appendix 1: WADA consent form; Athlete Information Notice) seems sparse at best. This, coupled with potentially coercive, or at least highly pressured environments, might be cause to question whether or not a particular athlete is sufficiently informed about their 'participation' to engage the right to withdraw. Specific informed consent is not a prerequisite of the RTW but informedness with regard to being part of a research project or cohort is. It is important to note once again that informedness requires both information and understanding. Simply providing a consent form with the basic legally compliant information is not sufficient to discharge the duty owed to athletes by those seeking consent to use their samples and data. Understanding must be checked and where it is not clear, then additional time and information should be provided. If we consider this in the context of seeking consent to testing and research using the sample once testing is complete, then we begin to see how limited the scope for informedness, especially for young, new, or second language athletes, is.

In addition to the issues raised so far, the non-exhaustible nature of data means that, even if a biobank were able to return it to its source, that removal is not necessarily meaningful as

others could still hold copies. Whereas if a material sample were to be given back or destroyed, it is finite; although data obtained from the sample could conceivably still exist, the thing itself would not. This matters for the actual withdrawal and for the perception of participants or data contributors regarding what is possible. Completeness assumes that in biobanks withdrawal includes the destruction of samples or return of samples to donor, and erasure of data. Returning data to the contributor is not discussed in the same way as samples because data may have been created or put together in new ways by researchers searching datasets. One option might be to offer contributors the option to anonymise data/samples with either permission to generate new data from the existing resource, or no permission to generate, but only to use what is already there. It should be noted that total anonymisation means that it is not possible to link to outside data or to gain new information on the contributor. This therefore, protects contributor privacy and means that she is no longer involved in research, but her data are still usable. This limits the utility of the data and in particular where the aim is to discover information by interrogating linked data sets, for example linking health records with travel statistics to understand how the mode of transport is related to overall health or specific health outcomes. Linkage of e.g., health or doping control data with other kinds of data may increase risk of identification or be of concern in other ways, for example exposing lifestyle choices or leading to research questions that do not align with the moral world of a participant or contributor. For these reasons the right to withdraw for any reason or not to give a reason at all becomes even more important.

The traditional approach to withdrawal in research interactions means not asking for reasons for withdrawal or informing people of the consequences of their withdrawal for the dataset or wider research project. In fact, it has been considered wrong to tell people of the wider implications of their withdrawing from research, due to the potential for undue influence and undermining of autonomous choice making. It can be argued that this is less of a concern in research biobanking due to the lack of personal power dynamic to influence decisions, such as might be experienced in clinical research, and there is usually no direct personal impact from withdrawal although we might include the expectation of information about their own genomic health or family disease traits, where available, as that may be considered a benefit to participation and therefore a loss (of potential informational value) if a person withdraws their data and no longer gains that information.

We might consider removing the right to withdraw entirely. This might be complete (ongoing data gathering and generation allowed) or partial (no further gathering, but ongoing

generation from samples allowed). Complete absence of the RTW would mean that even where there is fundamental disagreement with biobank work or study principles, a person is locked in to participating, or allowing their existing data to be used. This may seem to be contrary to the basic tenets of research ethics in terms of respect for autonomy and the right to make free choices, however it supports societal goals and may increase the potential benefits of research by reducing attrition. It could also be argued to be choice-respecting where a person has signed up to the option not to be able to withdraw. This tension refers back to key themes in the discussion of appropriate consent models and can be reduced further to a consideration of ends and means. At this point in time, in a society such as the UK, it seems unacceptable to remove the right to withdraw entirely due to the prioritisation of individual rights and freedoms, thereby disregarding the social value of contribution to research. There are practical as well as ethical challenges, for example removing the right to withdraw might lead to lower numbers of people agreeing to contribute in the first place, negating positive impact of the retention of those already in a cohort.

Partial withdrawal is similar to other social endeavours, where a person may withdraw from future activity but not remove past contributions (Holm & Ploug, 2017). This seems to be an appropriate model for research uses of ADAMS data, given that anonymization makes a more complete kind of withdrawal extremely difficult or even impossible. Also, in order to enact withdrawal, there would need to be retention of some amount of data in order to keep a record of the person having withdrawn so that no further data are used for research. Data retention may also be necessary for evaluation of protections and quality assurance, both necessary components of research management that can support ethical practice.

Quality Assurance (QA)work is regularly carried out by labs and other actors within WADA. It is a way to monitor and assess the standards of a practice, for example research. QA activities do not require the same protections as research and are one of the types of purposes for which, in general, data may be used without further consent from contributors. As Joly et al (2016) note, in practice QA and data research activity can look similar and share some risks. They are largely differentiated based on purpose or intent, both of which are hard to be clear about in open ended data research. The Health Research Authority states that the 'the intent of research is to find out what you should be doing', and the intent of QA is to find out' whether it is working' (HRA, 2009). Understanding the difference in open ended or undetermined uses of data is important because it will support the development of systems that reduce the possibility of conflation of QA with research either in error, or as a means to

circumvent ethical oversight or restrictions. Such oversight and boundaries on what is considered to be ethical in research are grounded in conceptions of risk and balancing risk of harms against potential benefits: a discussion of risks relating to biobank and data-based research follows.

6.6 Risks

As ways of analyzing and linking meta-data become ever more sophisticated, the ability to infer information about a group or individual increases even where the data points themselves are not accessed. Even partial data can be combined to create a usable or identifiable profile. Privacy risks exist for individuals whose data are used, but there are also relational risks i.e. the privacy of others that are linked to the participant and about whom data might be indirectly revealed. This is particularly the case where genetic data are derived from the sample, or genetic information inferred from data (Deznabi et al, 2017). There is potential for discrimination based on test results or ADRCs in an athlete's home country even if such discrimination may be legislated against where the data are processed. These concerns are heightened where the data contributing populations are small and known to each other due to the generally close and intensely competitive nature of elite sports populations, where athletes may well be familiar with each other's training and health information. The elite sport setting presents a range of challenges for the ethical use of even fully anonymized data. For these reasons risks to privacy tend to be at the forefront of discussions on the governance of biobank and data research, however they are not the only type of risk or concern requiring consideration.

Non-privacy risks include individually held reasonable objections to uses on a number of grounds including religion and cultural appropriateness, the right to self-determine. There may also be group risks if datasets are anonymized and de-linked, access and uses are governed appropriately and therefore risks of harm to the athletes from whom the data are taken are minimised then we might consider whether consent for secondary research is needed at all. It may be useful to consider the approach of the field of sports science more generally with regard to ethics for new uses of ADAMS data: 'Data are routinely collected from individuals for various purposes. For example, sport scientists may monitor physiological function of an athlete in order for him or her to gain an edge over their rivals. Data collected exclusively for one purpose cannot be used for another (research) purpose where specific consent per use is required, unless consent for the use in research is

subsequently given and the research ethically approved. An exception to this would be where the 'data collected for the primary purpose is anonymized prior to use in a research study (second purpose) which has ethical approval' (Harris et al, 2012:1027). In this approach the ethical justifiability of using data for purposes other than those to which consent was initially given is based on anonymization of the data concerned and the potential public health benefits of the intended research. This does not seem sufficient, particularly in the case of small, captive populations such as the athlete populations whose data are stored in ADAMS. Where populations are both small and known to each other, the risks of identification- accidental or deliberate- may increase significantly, though actual risk is also determined by the access and management of the data. Additionally, the number of people affected by an information leak may vary. If I compete in a team sport for example, my data might expose information about my team mates that they have not given consent to or may even not be aware is being used for research. A combination of data security, anonymization and good quality, accessible information with a broad consent model would allow sufficient flexibility and retain the opportunity to choose to contribute beyond the data that is retained for WADA's purposes. There would need to be clarity about the separation, different permissions and uses for data held for 'core business' where that includes limited research and quality assurance activity and data able to be used for wider research purposes including potential access by external parties.

In the case of ADAMS, athletes have given consent to processing and storage, access to their doping control related data, consent having been sought at the point of testing. As set out in the consent form 'The Testing Authority will use the ADAMS data-management system to process and manage my Doping Control related data, and disclose it to authorized recipients, (for instance, designated national anti-doping organizations, international or national sporting federations, major games organizers, and WADA). WADA-accredited laboratories will also use ADAMS to process my laboratory test results, but shall only have access to de-identified, key coded data that will not disclose my identity' (WADA, 2021.) The consent process set out here allows WADA to 'disclose it to authorized recipients', it referring to athlete data managed in ADAMS. This is not a sufficient consent to all potential secondary research uses of data, but as secondary uses have not yet been allowed this presents an opportunity to examine all the potential means of ensuring ethical conduct and move towards developing appropriate processes.

In many jurisdictions anonymized data may be legally processed without consent, but this seems to fall short of the trust and integrity that form part of WADA's values. Transparency and associated trust are of particular importance where athletes are consistently expected to provide huge amounts of personal information, such as their whereabouts and doping test results. Additionally, there are shifts between and within cultures and legislative regimes with regard to how anonymized data are dealt with. This indicates a need to further interrogate the assumption that anonymized data is risk free or 'minimal risk' and that the most important risk for participants is to privacy. Perception of what constitutes a significant threat to privacy, and the impact that may follow, can depend on the nature of the information that might be disclosed. Although it's a privacy breach for one person to find out and tell others 'sensitive information' about a person, another may not be so concerned. Disclosure of test results in doping control offers an example of these differing levels of concern with some athletes voluntarily disclosing information before they are required to, though the motivations in anti-doping may be context-specific. There are implications of using data derived from human tissue and not originally consented for research- in research that may well not benefit the athletes or even the athlete community directly. The athlete doping control consent form contains a paragraph regarding research uses that allows 'any WADA accredited laboratory for anti-doping research of any type, provided that it can no longer be identified as my sample' (WADA, 2021) stating that there will be no implications should an athlete refuse to consent to their data being used for research (within WADA). Where an athlete does not agree to research WADA allows the use of aggregated data only. The consent does not include third party access to ADAMS, nor does it specifically reference data research.

The fact that data have been permanently de-linked and de-identified goes in hand with the inability to re-contact for consent per new proposed use of data, should that be deemed the most appropriate pathway. Ordinarily, where a person has consented to research using their data, and the data are identifiable, there exists a duty to report clinically significant, actionable findings (within given parameters). The importance placed on this is reflected in discussions of the 'right not to know', the implication being that unless a person chooses not to be told, it is the duty of the researcher to make all reasonable attempts to make the participant aware of incidental findings. There is, however, no single agreed strategy for genetic and other medical data even where re-contact via 'breaking the code' or using the

keyholder to re-identify for the purposes of informing of findings is possible and deemed to be justified on medical grounds (Thorogood et al 2014).

In the case of ADAMS data, re-contact seems to be impossible due to the anonymization process. This is reassuring to many, as it appears to decrease risk to privacy and therefore potential abuses of the data. However, it also means that, should incidental findings be discovered, there is no way to report them back to the person to whom they relate. The 'participant' would likely be unaware that the investigation leading to a result had taken place. This may have adverse consequences for researchers who detect such findings and experience conflict at not being able to inform the data originator(s) in addition to the potential consequences for an athlete who potentially does not receive information pertaining to a serious health risk.

Athletes are required to give consent to the collection and uses of their data. They are unable to compete if they refuse to give consent to data processing, as doping control processes cannot be carried out without processing the data. Given this significant potential cost to non-compliance with a consent request, it is questionable whether valid specific informed consent is possible in these circumstances. There are many circumstances in which a person might be asked to consent to a thing, for example, data processing, where it is possible to freely choose to accept the terms or not and therefore access a service or not. Given the complex and intimate nature of the relationship between the ability to compete in their sport, and livelihood, identity, we might think that the decision for an athlete to accept terms or not goes beyond a simple choice. If an elite athlete who has spent many years and committed a significant proportion of time, money and the efforts of others to getting to a level of performance at which it is required to have an ABP and to have data stored and processed by ADAMS and other agencies, then it seems that the 'choice' to say no is in fact not a free one. Where a refusal to allow processing and storage of doping control data has the likely consequence of exclusion from participation in my chosen sport(s) there is little doubt that athletes experience pressure to conform to WADA requirements even where they disagree with them. It is not clear how this might affect their decision-making regarding research consent nor whether it is ethically problematic in its own right. In order to try and understand both of these aspects we must consider the nature and scope of the influence/coercion/pressure/incentive and how consent is challenged. It seems reasonable to say that decision making almost always occurs in constrained circumstances of some kind, but this does not tell us whether or not those constraints are justified or problematic nor does

it show how. As discussed in Section 6.4, voluntariness is fundamental to valid consent and so understanding the ways, if any, in which the particular dynamics of the WADA-athlete relationship affect this is key.

With the increasing inclusion of genetic data (includes genomic data) in anti-doping research and testing, it is important to be clear about the ways in which genetic and non-genetic data may need different ethical or regulatory treatment. For the GDPR, Genetic data are defined as

> 'personal data relating to the inherited or acquired genetic characteristics of a natural person which give unique information about the physiology or the health of that natural person and which result, in particular, from an analysis of a biological sample from the natural person in question' (GDPR, s. 4(13)).

A relatively new type of risk of identification arises via epigenetic research and the inference of information from genetically related data. It is possible to infer genetic information about a person based on phenotypic information, particularly so for conditions that present with distinctive phenotypic traits, such as Huntington's. Genetic information may also be inferred from protein levels and other biochemical markers present in sample-derived data. Where this information is linked to even a small number of additional data points, for example a sport category that has few participants in a given geographical region or population there is an increased risk of identification or at least it may be possible to narrow down significantly. This matters not just for its own sake, but due to the possible consequences of being (more) identifiable. These include potential accidental or malicious disclosure of genetic or other health information. As it is not possible to report back to individual athletes due to anonymization processes, information may be put together and could possibly be made known without ethical protections or means of harm mitigation for those affected. There exists the additional risk of identifying relatives of a person whose data has been used in such research. Therefore, the possibility of exposing someone who has not even given data and may in fact have no idea that their genetic relative has done so. Trust impacts on wider relationships between athletes and WADA as well athletes and research, with potential adverse consequences beyond doping control where trust is perceived to be broken. The system of doping control measures and adherence to WADA requirements requires some measure of trust. If athletes do not believe that their data is safe, or that actions are taken for the good of sport and their communities, then the social licence to manage anti-doping efforts is at risk. This in addition to the psychological and moral risks to athletes and to those

working in anti-doping if there is a breakdown of trust. As discussed, the power imbalances and the mandatory nature of doping testing in sport challenge the relationships between athletes, ADOs and WADA. One important aspect in this complex network is the diversity of athletes and the implications of diversity (or lack thereof) in research data, discussed below.

6.7 Diversity

Much has been written about the lack of diversity in research databases, particularly those containing genetic data. Suggestions of potential ways to improve this situation involve increasing engagement with minority populations and therefore increasing the number and range of samples and/or data taken from those populations. There are good ethical and research reasons to do this: certain conditions are far more prevalent in some populations than others e.g. Diabetes and the metabolic syndromes in South Asian communities (Shah & Kanaya, 2014). There may also be relevant sporting and anti-doping research areas: drug susceptibility and athlete baselines for hormone levels can also differ by ethnicity. However, we should be extremely wary of racial profiling based on the conflation of social and biological characteristics, and of assigning disproportionate significance to one aspect of an athlete's physical or genetic make-up over another. The reduction of race to genetics is seen in sports research and wider discourse and sport is a highly visible example of the ways in which attributing a trait or ability to genes is overly simplistic and potentially harmful (Camporesi & McNamee, 2018). The complexity of interacting factors that have to combine to produce athletes able to compete at elite levels, those in the registered testing pool (RTP), for example should not be reduced to genetic and biological determinism.

The cultural positioning of sport; access to resources and training opportunities has a significant impact on whether an individual achieves success in the sporting arena. The ways in which ADAMS data might be used must be carefully examined to avoid continuation of these and other harmful tropes. The language of genetic determinism can be seen to perpetuate stereotypes of lazy but talented persons of particular ethnicities versus the 'hard work' of others (McNamee & Camporesi, 2018). Research needs to be open to all findings, but awareness of biases in for example design and reporting is key. Sharing the benefits of any secondary research with the communities who contributed the data must also be managed carefully. In the case of ADAMS, we might reasonably take the community to mean athletes

generally, who potentially benefit from anti-doping research improving conditions in sport. This will of course include both those who consented to research and those who did not. For wider biomedical research uses on anonymised data the benefits are aimed at improving lives in society more generally. This benefit sharing is the responsibility of the researchers, but also of WADA as the values-based organisation that manages the data and controls access. WADA has a significant role to play in the ethical governance of research using ADAMS data in creating expectations and enforcing adherence to guidelines on best practice. Governance will need to cover all aspects of ethical research conduct including conflicts of interest.

Potential conflicts of interest may arise where research uses are proposed either by those with an affiliation to WADA/ADAMS or those with stakes in commercial companies that might develop patents from the research conducted using the ADAMS data. Possible conflicts of interest arising from multiple affiliations or political pressures can also arise, as discussed earlier. A clear protocol for declaring possible conflicts of interest already exists in both WADA and wider research communities, however the lines are less well drawn when it comes to secondary uses of data and it would serve WADA well to develop a specific protocol. Data research is generally perceived as being lower risk than that conducted on tissue by both researchers (data are inexhaustible, compared with the finite nature of tissue, for example) and 'participants' (tissue is a part of my body, whereas data is external, other, although intuitively many believe that they own their data) (Jones et al. 2017) and therefore ethical oversight needs to be proactive whilst still allowing for research to be conducted. Overly cautious or restrictive governance can have a stifling effect which may protect participants in the short term, but means that potential benefits of research do not arise. The balance of protecting athlete interests and facilitating research is not even, as although any research benefits and harms are only potential, risk itself can pose a threat to wellbeing. Additionally, local ethics review is required prior to approval of studies to be funded by WADA and in recognition of ongoing difficulties in obtaining ethical approval prior to funding, the WADA ethics committee produced a questionnaire for proposals to use to assist in the process. As mentioned, in some locations ethics oversight is not required for secondary research on anonymised data, and in many cases oversight might be via a data access committee rather than an IRB. The policies currently in place at WADA refer to research conducted using samples derived from human tissues and do not explicitly cover secondary research.

WADA directly funds anti-doping research undertaken by accredited laboratories. This refers to laboratory-based research using tissue and urine samples originally taken for testing as well as samples taken directly for research. It does not include use of data in ADAMS. As of the time of writing, there has only been one external/third party use of ADAMS data and that research was described by WADA as 'tightly controlled with limited access being granted on site at WADA HQ in Montreal and an external verification of protocol required prior to access' (Dr O. Rabin, personal communication, 2018).

Dr Olivier Rabin states that 'WADA would potentially be open to more uses of the anonymized, permanently de-linked data in ADAMS but as yet there is no protocol in place for what uses might be allowed, or how that might be managed in terms of both consent and types of research' (personal communication, Sept 2018). WADA do not explicitly control or restrict the types of research uses that might be allowed, except that there would have to be a 'significant public interest justification as well as a very high-quality proposed research project, for third party uses that were not related to anti-doping movement' (Dr O. Rabin, personal communication Sept 2018). Third party uses related to anti-doping seem more straightforward then. If the researchers can provide verifiable protocols that meet WADA standards, and the proposed subject for research is agreeable to WADA's scientific leadership then it might seem as though few barriers to secondary use of ADAMS data exist.

The increased risks to privacy related to research conducted in a small or easily identifiable group, such as elite sporting populations, is mentioned in the Additional protocol concerning biomedical research of the Oviedo Convention. Para 3 of the Convention states that

> 'Such risk may exist even if the data is anonymized because the group to which the source belongs to is still identifiable'. It then goes on to say 'This protocol does not address research on archived biological materials or personal data. However, this does not necessarily exclude biomedical research based on archived personal data or biological materials from submission to an ethics committee'
>
> (Council of Europe (Oviedo) Convention on Human Rights and Biomedicine, 1997)

While the transfer of data and potential secondary uses of ADAMS data for research may not be directly governed by the Oviedo Convention, or the GDPR due to the data being anonymized, it seems reasonable to seek guidance from instruments that govern much of the activity related to the research. In so doing, the geopolitical influences on those instruments

and on the anti-doping movement itself must be acknowledged. Sport and research are both situated in the wider world and the complexity of both contexts.

Ethical governance of secondary uses of human-derived data should aim to balance current and future acts of self-determination and the interests of the public and private individuals. Regulation is a guide to what has been socially acceptable but it is not the whole picture. Privacy and autonomy matter, but so does gaining new knowledge and applying it to the improvement of society as whole, including the interest groups relevant to a specific context e.g., athletes subject to anti-doing regulation.

The impact on autonomy and freedom to choose is minimised by good communication from the outset, in partnership with transparent and accessible governance processes that demonstrate trustworthiness and it is this model that WADA should seek to emulate, should they decide to open ADAMS to third party researchers for uses beyond anti-doping.

In a survey asking about research uses of anti-doping samples and data, WADA accredited laboratory-based respondents said they had not needed to use samples for which there was no research consent due to sufficient availability of samples with consent. They also explicitly mentioned that they felt that using such samples would be 'disrespecting the wishes of the athletes' (Devriendt et al, 2019:2-3). Respondents prioritise consent and see it is as a legitimizing or permission-giving exercise to be respected. However, it does not indicate whether samples without research consent would have been used if those researchers felt it necessary, nor are there criteria that describe how 'necessary' is defined or decided and by whom, in that context.

Where requirements are not clear it is likely that those managing data for research will err on the side of caution, taking a more restrictive approach than they might if consent and procedures were clearly defined. Two survey respondents claimed that they would 'make exceptions for particularly interesting samples of athletes who have tested positive for doping' (Devriendt et al, 2019:4). This raises questions about the basis for making decisions about data use and whether or not consent is needed. If the decision to use data is based on the protection of athlete autonomy and the right to make their own choices about whether or not their samples or data are used, then whether or not the athlete has doped should be immaterial. However, if the decision basis is scientific interest, then we move away from consent as the gateway to the use of athlete data or samples for research. In that scenario the grounds for allowing research without specific consent seem to be the potential for interesting

findings (and the possible future goods that might be derived from those findings) and that the athlete from whom the sample was taken, has tested positive for a banned substance. This approach raises ethical questions: just because an athlete has violated doping rules, they should not forfeit their right to have their consent sought to the use of their data- in a system that prioritizes individual consent. It may be that specific informed consent is not the most appropriate model in general, but there should not be a different rule for those with an ADRV and those without. The main motivation for examining all of the issues so far is the potential accessing of ADAMS' data for research by external, or third party, researchers. Some key challenges that may arise in allowing such access are discussed below.

6.8 Third party access to ADAMS

If third party researchers have to specify uses within parameters set by WADA, then a critical consideration will be how much control WADA want to retain over research purposes once data have been accessed. The decision to allow access could be based on meeting requirements for governance and access control rather than proposed uses. WADA state they do not intend to use data to track substance use in an individual athlete and have stated that they will not allow any third-party researchers to do so either (WADA, 2021). This allays some concern about the potential use of athlete data in ADAMS as a means to further surveil athletes.

It would be difficult for WADA to require the research groups to publish their findings where they are simply facilitating access with no further controls. However, it should be possible to have open access written into the funding criteria (where WADA fund the research) or access requirements. WADA will continue to discuss the future of access to research, including open access. This has potential implications for research based on ADAMS data, especially because WADA 'owns' the data and therefore can decide what approach to sharing it want to take. Various access models exist, for example the SAIL database operates on a trusted third-party system, as a Trusted Research Environment (TRE) where data are not usually removed from the TRE, but accredited researchers have controlled access (www.sail.ac.uk), but these models provoke questions of how researchers are authenticated, what appeal process they have if they are unsuccessful, and to whom. An in-house authentication system could be used to include those who conform to WADA's ideology and of greater concern, to exclude those who disagree, or who might be considered more likely to publish work that challenges the status quo. If access is widened to more general biomedical research using the ADAMS data then something like the registered access approach that has independent oversight in a similar

way to Data Access Committees may be appropriate. The need is for a way to support access by legitimate third parties whilst remaining confident that only appropriate access is given to athlete data. This could include review of the intended uses of the data by the researcher seeking access, but leave the extent to which uses are controlled to be decided by individual entities. This raises an interesting tension known to exist in open ended population data research: between oversight requiring some level of specificity, and the need to keep potential research directions open to be able to capture as much as possible. This is different from the development and then testing of a hypothesis of traditional methods: inductive rather than deductive.

There are challenges in verifying institutions- in particular for those working outside of traditional research arenas, which may be more the case in sports related research than other fields. In part because of the use of commercial testing laboratories. There may be additional ethical considerations regarding research proposed by commercial companies, or partnerships between commercial ventures and academic or other researcher partners. Certainly, public consultations in other research arenas have shown that people are less accepting of for-profit research than they are of publicly funded non-profit work (Middleton et al, 2018). It should be noted that this is somewhat of an incorrect distinction in the modern research world. For example, public-private partnerships exist in many areas of health-related research and biobanking and researchers in public institutions may 'spin-off' profit-making endeavours from their research.

WADA may not wish to involve itself in the intended uses of ADAMS data, but solely to accredit researchers as being suitable to have access to data, however there is a duty set out in the GDPR, DPA 2018 that may offer guidance to WADA in general (and be a legally binding duty regarding the data of those athletes who come under the legislation). As custodian of the data contributed in the name of combatting doping, and by athletes who may be wholly unfamiliar with the mechanics and ethics of research using their data: These same athletes may now find themselves to be research 'participants', although data contributors seem a more accurate term, as there is no participatory or reciprocal relationship. Prior to access being granted, work must be carried out to establish how far WADA's duty might go in terms of ensuring responsible access and use, but also how researchers are accredited. For example, there is increasing literature on the non-neutrality of the algorithms and analytical techniques used in research based on data. Biases that may become particularly apparent in heterogeneous cohorts such as those who have data stored in ADAMS. Racial and gender

biases are perhaps the most obvious and pervasive (Criado-Perez, 2018; Benjamin, 2016, 2019). It is important to determine what duty, if any, is owed by WADA to those who contributed data solely in order to compete in their chosen sport, and for whom a decision to allow secondary uses has been taken on their behalf. Whilst persons may not have property rights in data, there is a general assumption that they do retain some kind of relationship to their data after it has been given to process. This seems to be particularly the case where the data come from tissue or health information, hence the special protections afforded to such data. R

Potential research Uses

Potential uses for ADAMS data within anti-doping research include identification of gene doping or somatic gene editing, which WADA is aware is commonly offered to athletes. It is, however, noted that there is a very low likelihood of successful enhancement (Borry, 2018). Gene or cell doping is defined by WADA as "the non-therapeutic use of genes, genetic elements and/or cells that have the capacity to enhance athletic performance"(WADA, 2019). An example of a somatic editing target in sport is myostatin inhibitors, targeted because they are linked with increased muscle mass (Sharp et al, 2014). Follistatin, a myostatin antagonist, was added to the WADA Prohibited list in 2019, as well as being classified as a supplement. Gene editing is a potential health risk as long term and off-target effects are unknown for many potential target genes. It also contravenes the spirit of sport and counts as an ADRV whether enhancing performance or not. Another potential research use of ADAMS data is the detection of fake and low-quality drugs. Substances including injectable testosterone, synthetic AAS, non-AAS hormones, and other adjunctive therapies can be purchased over the Internet without a prescription, and delivered to the buyer. A 2018 study confirmed that the majority of AAS obtained over the Internet are ‘manufactured by unregulated international pharmacies of unknown quality or content’ (McBride et al, 2018).

There is a large identified global market in fake substances, with production concentrated across India and China. The best-known classes of these counterfeit pharmaceuticals in the sporting world include analgesics and anabolic steroids (O. Rabin, personal communication, 2018, Brennan et al 2013, Coopman & Cordonnier, 2018). If ADAMS data were used to identify fake and/or banned substances, it should not be linked back to a specific athlete but used to warn WADA accredited testing labs of their existence. This research is an example of

data linkage, in this case potentially between ‘dark net’ data and illicit transactions with biomarker and other biological data from ABPs in ADAMS. There are multiple potential avenues for exposure of agents and for risk to reputation, psychological and professional harms in this area of research. Not only is there the risk of doping violations, but also potential criminal prosecution, for the trafficking of fake drugs rather than doping. This may have consequences beyond the individual athlete or support personnel.

Inferring probable characteristics or actions of an individual based on indirect data and the data of persons linked to an athlete is possible. For example, the whereabouts information of teammates may indicate the whereabouts of a person not in the database, but who is known to have been in the same place as those in the database. The same may be true for supplement use and other substances where it is known that teams eat together or were competing in a particular place and the menu at their accommodation is not deemed to be sensitive information and therefore readily accessible. This is analogous to genetic information derived from samples given for testing that can be used to identify relatives, or to discover predispositions for a number of conditions that have familial inheritance. There exists the potential to expose sensitive health information, or to infer it from anonymized or partial data. Such exposure or inference would potentially affect those related to persons in the database who have not consented to their genetic information being used for any purpose and who may well be unaware of the original reason for data being in ADAMS, much less secondary use of such data by third party researchers.

WADA’s ideas for the future exploration of ADAMS as a research resource include improving how athletes are informed about the right to withdraw, including explanation of how this right is complicated by the anonymization of data; standardization of anonymization procedures; hormone related research using ABP data and further consideration of gene editing and gene doping. In information there should be illustration of the difference between the rights to privacy, to withdraw and to be forgotten. For example, the right to privacy refers to information that has not yet been made available, whereas the right to be forgotten refers to the taking down of data that are already in the public sphere. It originally referred solely to online information, but the principle is worth considering here in slightly expanded form due to public and media interest in doping and the global profiles of big sporting events. The wealth of publicly available information adds a further dimension to the privacy risks of

accessing ADAMS data due to the increased potential for linkage of 'non-sensitive' data with e.g. ABP information in order to re-identify or to infer new information about a person. There are social and professional risks to certain kinds of information being made public and these are at the heart of the harms of privacy. It is not simply the sharing of data or information but the actions or omissions or exclusions that may follow.

The 2019 call for WADA research grant applications focused on the application of AI to big data with regard to identifying doping practices or 'actions suggesting attempts' to subvert anti-doping rules. Establishing the "Attempted Use" of a Prohibited Substance or a Prohibited Method requires proof of the athlete's intent. The fact that intent may be required to prove this particular anti-doping rule violation 'does not undermine the Strict Liability principle established for violations of Article 2.1 and violations of Article 2.2 in respect of Use of a Prohibited Substance or Prohibited Method' (WADC, 2018)

The phrasing seems to imply surveillance and potential for pre-emptive moves against those suspected of attempting to violate the rules, based on interrogation of data. This is in opposition to claims that third party access to ADAMS data would not be allowed for surveillance of athletes or targeting of anti-doping efforts against an individual or group (Rabin, personal communication, 2018). The WADA intelligence and investigations policy section 10 states that electronic data used for an investigation is securely stored within WADA, but separate from any other databases. It is governed by the ISPPPI and international law. The call for proposals goes beyond anti-doping, seeking work '…regarding the impact of the use of artificial intelligence and big data collection on numerous facets of society, and the overarching questions that this technological progress raises in terms of ethics, law and good practices' (WADA, 2018). WADA's efforts to fund research into how to responsibly manage biometric data and subsequent dissemination are to be welcomed, but it is worth noting the requirement that 'analysis will be based on data selected by WADA (and, if applicable, propose new sources of data, both external (public) and internal)' (WADA, 2018). More information is needed regarding the data selected, how the selection will be done and by whom.

Even without the application of AI to the data, there are numerous potential uses of the ADAMS data beyond anti-doping or even sports research more widely. An important question to consider is not simply what types of research would be ethically justifiable, as

well as approved by WADA, but in what ways the types of proposed research might alter how we think about data governance. Doping control, specifically testing, is not considered to be medical, nor is the research based on those samples immediately recognizable as medical research and is therefore not subject to the same regulation and ethical oversight. However, the actions taken and the actors involved are very similar to those considered to be 'medical research'. We therefore need to consider what the ethical implications might be when something that looks like medical research is conducted outside the bounds of medical or health research controls (Joly et al, 2016). If data derived from doping controls and stored for the same purposes are later interrogated for unrelated purposes, can this be justified under the broad umbrella of public health or public interest? (Devriendt 2019).

Secondary use of data may be in the interests of athletes and the wider public not only by virtue of potential benefits from research, but because of the reduction in expense and time needed to conduct the work due to lowering the need for new data and samples to be taken (Jones et al, 2017). An athlete who has given consent to their data being processed may well agree with the need for Whereabouts rules or the ABP in order to be able to compete in 'clean sport' however it is highly unlikely that they have knowledge of the types of uses to which that data might be put if research access is granted. A way to ameliorate this gap in knowledge that cannot be realistically filled without time consuming and repeat work from both researchers and 'participants' might be to consent to governance of research rather than research itself. This idea is further explored in Chapter 4 (See also Sheehan et al, 2019).

6.9 Conclusion

Anonymization, in hand with good governance and independent ethics oversight of proposed uses may mean that risks to privacy are minimized, but that does not resolve the challenges of self-determination with regard to data and sample use, or incidental findings reporting. The right to self-determination in this context refers to the right to choose to what purpose 'your' data is used. People may have legitimate personal concerns about certain research areas, or simply wish to be asked before their samples and data are used. Technically, this does happen as there is the option to opt-out of allowing data to be stored and processed by WADA however by not giving consent, athletes risk not being able to compete, at the potential costs discussed earlier. There are well documented differences in the way that people perceive types of research (Dye et al, 2016; Middleton, 2017). Research leading to the development of

commercial patents from which neither the athlete data originators nor WADA derive benefit might be considered less favorably than research into for example arthritis, both a common condition in the general public and one to which highly active populations may be more prone in later years (Gouttebarge et al, 2015).

Empirical work is needed to better understand athlete attitudes to research generally and to secondary uses in particular. Designing governance and processes in conversation with the 'participant' population is good ethical practice and may alleviate some concerns regarding research activity. Some argue that there exists a right, or even obligation to engage in scientific research as well as a separate right to benefit from it (Harris, 2005 Knoppers, 2009; UNDHR, 1947) which might justify secondary uses of ADAMS data for research both relating to anti-doping and beyond. A starting point for ethical control of secondary uses may be to require that third party research demonstrates or adheres to WADA's core values (WADA website, 2019) and that researchers are held accountable for this by WADA. Proactive support for positive behaviours should be coupled with sanctions for those who contravene agreed boundaries and conduct. Such an approach, in conjunction with consent to governance, transparency and the separation of consent to research from other consent requests, specifically doping control activity, will facilitate an ethics-embedded research environment that aims to balance relevant interests: enabling uses of data to benefit athletes and the wider public, and protects athletes' privacy and autonomy. It is not possible to eliminate risk from research entirely, but embedding independent oversight together with transparent processes and using existing proven systems should create ethical and research-supportive conditions.

7. Public involvement and engagement

This chapter will investigate some of the ways in which public involvement and engagement (PIE), in particular deliberative approaches, might facilitate trust and understanding of public interests and how they shift over time and between settings. Specifically, how public involvement is of particular importance in the context of large scale (longitudinal) projects that use samples and data because of the disconnect that exists between 'participants' and the research, and often between the public and research. This is particularly the case for research where consent is not required, i.e. anonymised data, or where a research exemption is applied. When public involvement includes a pluralistic and inclusive approach to engagement, operational and ethical harmonization can be facilitated, even across large-scale multi-jurisdictional projects. WADA-ADAMS is a setting where no engagement regarding research uses of data has yet occurred (with athlete populations) and there is a low-trust problem, therefore this presents an opportunity to engage with interest groups and develop policy ahead of allowing research uses of samples and data originally taken for anti-doping purposes. Overall, this chapter argues that embedding public engagement and involvement into research design from the outset can both improve the quality and sustainability of research and is a more ethical way to approach both potential research access to ADAMS and design of population biobanking in general.

There is a sizeable academic and practitioner literature on public involvement and engagement (hereafter PIE) around research and uses of data. This includes a range of definitions for relevant terms as well as principles and strategy documents. Some key examples are given here.

The National Coordinating Centre for Public Engagement (NCCPE) defines engagement in the following way: 'Public engagement describes the myriad of ways in which the activity and benefits of higher education and research can be shared with the public. Engagement is by definition a two-way process, involving interaction and listening, with the goal of generating mutual benefit' (NCCPE, 2021). Although engagement and involvement are sometimes used interchangeably, involvement may include engagement and consultation as part of more cooperative work with publics during the research process. National Institute for Health Research (NIHR) Centre for Engagement and Dissemination distinguishes between

three key terms: Involvement, Participation and Engagement, and has produced guiding principles and strategy based on public consultation (NIHR, 2021). Thirdly the UK Public Involvement Standards Development Partnership, which draws expertise from the four nations, defines involvement as 'Research being carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them' (NIHR, INVOLVE, 2017). Participation is 'an infinitely malleable concept' (Cornwall, 2010: 296) that is used across a huge range of disciplines and activity. As Cornwall notes it can be reframed to mean almost anything that someone using it needs it to. A useful way to consider the kinds of activity that can justifiably be called participation is comparatively, with reference to Arnstein's Ladder (1969) (Fig.1, p69). The way that participation in PIE is used in this thesis is broadly captured by 'rungs' 6-8: partnership, delegation to citizen control.

The NIHR partnership has produced a set of standards for organizations to meet and use to build upon in the design and implementation of their own strategies. These are:

1. a framework for what good public involvement in research looks like and are adaptable to different situations;

2. designed to encourage reflection and learning, including where lessons have been learned when public involvement has failed to lead to expected outcomes;

3. a tool to help people and organizations identify what they are doing well, and what needs improving;

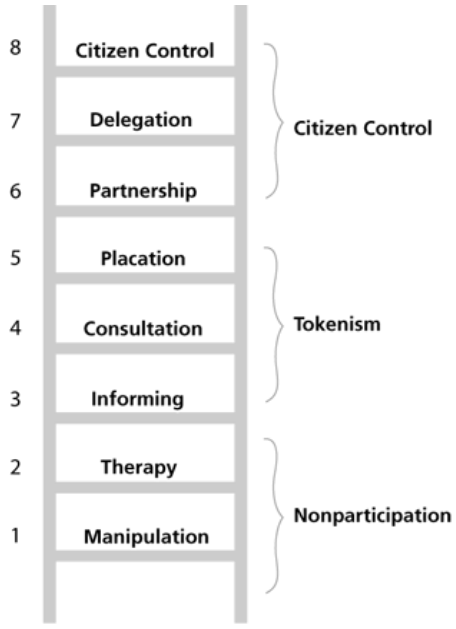
4. intended to be used with any method or approach to public involvement in research (NIHR, 2021)

This small sample demonstrates the wealth of existing work that can be used as a foundation for context-specific PIE design, working with relevant interest groups. Further work will be needed to assess the suitability of existing models in detail and decide, ideally with stakeholder input, how they need to be adapted or revised to work for the ADAMS context.

There is a general acceptance that some form of engagement is of benefit both for instrumental and ethical reasons and this is borne out of the increase in mandating of PIE by research funders and institutions (Wellcome, HDR UK, UKRC). What counts as PIE is subject to much debate, and criticism is rightly aimed at 'tick box exercises' that do not meaningfully engage but exist only to meet funder requirements or to seek validation of decisions that have previously been made, without opportunity for meaningful revisions.

The spectrum of PIE runs broadly from dissemination of information, for example sharing results, via increasing levels of involvement to co-production and co-creation (used interchangeably here). The model of a ladder of engagement which runs from complete control by citizens to non-participatory, paternalistic approaches has been in common use for decades (Fig. 1 Arnstein, 1969). Although it should be noted that in practice, PIE activity does not sit neatly on a linear scale. Additionally, methods from political science and participatory democracy are increasingly being utilised to support research and to engage with publics in priority setting, working towards policy recommendations for research and with policy receptors for the application of research. For simplicity those methods will be referred to as deliberative, acknowledging that the descriptor 'deliberative methods' describes a range of actions. Given the wide variation in types of research and contexts, it is appropriate that a range of tools and activities be available and considered valid in different settings. It is also necessary to assess which approaches may be most appropriate based on the specific aims of the PIE activity and in light of the particular context and group(s). This chapter examines the need and justifications for PIE, who should be involved and explores approaches that may be beneficial to the participants, potential research and the wider public.

Fig. 1.



Arnstein's Ladder (1969)
Degrees of Citizen Participation

7.1 PIE and Biobanks

A range of PIE activity is increasingly being implemented by biobanks around the world to close a perceived agency gap and work within the bounds of social acceptability. Examples include the (Canadian) BC Generations Project's adaptive governance structure that includes 'the structural incorporation of participant interests into governance via participant bodies' (O'Doherty et al, 2011; 372) and the UK Biobank's reflexive governance model that promotes wide-ranging and ongoing commitment to stakeholder engagement, noting that stakeholder engagement may, but does not necessarily, include the public (O'Doherty, Hawkins & Burgess, 2012).Although there are many types of biobanks, Dove et al. argue that a consensus is emerging in large scale, population-based biobank governance, stating

> 'the collective, public nature of a biobank's constitution and stored material in the form of data and samples militates strongly in favor of the active involvement of contributors in decisions regarding the allocation and stewardship of biobank resources' (2012:1).

Ethical norms that exist for the communication of research should be comprehensible to lay audiences and therefore must be both accessible and appropriately pitched. Good communication of research and research ethics and governance is not a 'nice to have' but is fundamental to ethical science. This is not the same claim that the public should be involved in the commissioning, design and conduct of research, but rather the two claims are intimately linked. At a minimum, open communication that encourages dialogue, should be embedded from the outset and ought to offer the opportunity for publics to understand and form an opinion about research, or proposed research. Where that is not the case, discussion of involvement and the use of terms such as 'social licence' to justify practices and imply public acceptability, may be rendered meaningless, or at least greatly reduced in power.

This chapter supports that claim and explores a range of approaches to PIE for the WADA ADAMS context in order to make recommendations for PIE that complements and informs governance, ethical oversight and the harmonization of approaches across borders.

7.2 Who are the public(s)?

In order to claim that research is justified on the grounds of public health or public interest, and when considering what role public involvement may have in research, a clear understanding of 'public' is needed. At a macro level, public refers to the whole of a given society, used to differentiate the experts or practitioners from the rest. The phrase 'publics' or

‘populations’ is used to reference the heterogeneous make-up of many societies and the need to consider the interests of particular groups as part of, but distinct from, the wider ‘general public’ (Boulianne, Chen & Kahane, 2020; Elstub & Escobar, 2020). It can also refer to specific interest groups whose data would be used for proposed research, for example, athletes whose data is stored in ADAMS. Proximately there is another ‘public’ who also have interests at stake: athletes and sporting participants who would be affected by the outcomes in anti-doping research. Beyond that, if broader biomedical research were conducted using ADAMS data, the relevant patient populations for particular conditions and their kin would be affected. In the case of multinational projects and populations, such as athletes subject to anti-doping restrictions, expansion of who is considered the relevant public may mean groups sharing characteristics but in multiple locations. Public(s) can also be used as a term of exclusion; an identifier of those with less, or less valued, knowledge than those validated as experts. That is not to say scientific or other research expertise is not a crucial part of the landscape, but that the definition and understanding of expertise is often too narrow. A good example of this is the anti-doping context: who knows the world of elite sport better than elite athletes? Who knows community grassroots sports better than those who organize and take part in it? Experiential expertise is of huge value when seeking to understand what is acceptable and justifiable in a particular context, for example the potential secondary (research) uses of data arising from anti-doping. WADA-ADAMS is also an interesting case because of the non-medical primary purpose of the data collection, with public health justification for anti-doping measures (WADA, 2020). These challenges will be explored further in Chapter 6. Calling something ‘public health’ (PH) might draw attention to both the problems and the solutions arising from systems and requiring preventative and mitigating actions at a population level (although this is not always the case, for example, obesity is still largely problematized at an individual level, despite strong evidence regarding socio-economic status and other societal factors (See Bombak, 2014; Young et al, 2016; Brady 2016). A normative issue in PH arises when a problem or condition is framed as being urgent or especially important and therefore responding to the problem is of moral importance that arises from the nature of the problem as well as from the harms it may cause. Doping in sport is one such issue and much of the discourse around doping and anti-doping measures refers to PH and public interests. PH might also refer to an increase in a problem or condition (e.g. recreational athlete doping) in a population. Where a problem threatens 'important values' particular kinds of intervention may be justified (Dawson & Verweij 2005:14) and this should include the research required to develop those interventions. For a given context e.g.

ADAMS research, understanding who the relevant public, and specific interest groups within the public are is fundamental to development of research in the public interest and even more the case for embedding meaningful PIE.

In the case of multi-national research, stakeholders include publics from a range of cultures, experiences and geographic locations. In thinking about who the public are in general research terms and per specific context, 'general public' has historically been used to differentiate experts and/or practitioners from the rest. As previously mentioned, the term 'public' can be a term of exclusion: an identifier of less or lesser knowledge and care should be taken to examine and define what kinds of knowledge and expertise are necessary and desirable for the specific situation. In considering the potential research uses of ADAMS data it would seem obvious that athletes and researchers should be key parties in decision making, but views on who else should be involved may differ according to the types of proposed research and who might conduct the work. Funding and timeframes also impact what is considered feasible and whilst these are valid considerations, care must be taken to distinguish them from ethical and governance ones. Just because something carries a cost or time burden, does not negate a strong ethical mandate, should one be present. Conversely, over-caution or overly complex systems of approval, for example, may place unnecessary barriers to the use of data or other research activity that presents few authentic concerns.

Before working at the level of proposed projects, establishing basic principles for the secondary uses of athlete data should be prioritized. This will require meaningful athlete involvement and engagement from the outset and deliberative methods may offer a pathway to understanding athlete attitudes and points of agreement and difference between stakeholders whilst working towards principles for research governance. Deliberation is a labour-intensive method that requires organizational and individual effort, facilitated discussions and learning. The aim of deliberative engagement, as part of a suite of work, would not only be to work towards creating principles for secondary research uses of ADAMS data, but also to demonstrate trustworthiness and work to earn trust with communities who have expressed distrust and concern over historic lack of transparency.

Who is considered to be the relevant public differs between research areas. For instance, a cancer study may want to recruit cancer patients to input into research design and to consider ethical questions, or it may include non-patients as well, given that cancer affects so many aspects of private and societal life. Cancer patients may be a 'special interest group' but they

are also members of society with multiple roles therein. The same logic applies to athletes as both primary stakeholders in anti-doping activity and (potential beneficiaries of) anti-doping research. The intersectional and often complex nature of people's identity and experience should be considered when deciding 'who is the public'. A relational approach that gives weight to different kinds of relevant experience may do better at capturing what matters to people and therefore what is deemed important in designing engagement and research. This must take place within the bounds of the applicable codes of conduct and other regulations. Understanding scope, purpose and clearly communicating such is key to effective and ethical engagement.

Public involvement can be seen as a means to establish what directions research can and should take within current normative bounds. This includes which ethical concerns are perceived to be most pressing and, where appropriate, how to design research to be effective, inclusive and gain the most potential benefit whilst minimizing potential harms. Care must be taken to avoid simply establishing preference and hearing the opinion of those involved in PIE. Make up of groups is also important but there are obvious limitations of e.g. the direct extrapolation of findings from small groups to a whole society. These include the representativeness of those involved in the engagement compared to society as a whole and the specific motivations for their involvement. Representation matters for more reasons than establishing permissibility or legitimization of proposed research. It is important in developing trust between participants, and between participants and facilitators or researchers and may feed into perceptions of organizational trustworthiness for the general public, researchers and institutions. Done badly, for example without prioritizing accessibility, inclusivity and representation, public involvement may exacerbate any pre-existing lack of trust and potentially create other issues such as withdrawal from ongoing research or backwards movement on previously accepted (or appearing to be) research activity (Erikainen et al, 2021).

Involving the public and special interest groups may be particularly important for research that collects and/or links large datasets, and all the more where those data were originally taken for other purposes e.g. whereabouts data from elite athletes, or linked health records data for biobanks (Erikainen et al, 2021). The importance arises due to the disconnect described between participants (more accurately described as contributors due to lack of active participation), their data and those types of research. Deliberative methods have been used extensively in biobanking and large cohort studies and are discussed below.

7.3 Deliberative Engagement

Deliberative engagement, based upon deliberation principles, has its roots in democracy and political science (Bachtiger et al, 2018; Elstub & Escobar, 2019). Recently, deliberative and deliberative-inspired approaches have been adopted into PIE for research, most commonly in the social sciences. In Arnstein's hierarchy (Fig.1) deliberation sits near to the top, being one of the most involved and cooperative methods used. Deliberation has no single agreed definition, but characteristics include (giving research participants) 'the opportunity to learn about a topic, engage in debate, and come to collective decisions on what policy should entail' (O'Doherty, Hawkins & Burgess, 2012).

Deliberative techniques may be useful in determining what is acceptable and how to construct governance, particularly for open-ended large-scale research endeavours. These techniques have been applied and evaluated in population biobanking for many years (O'Doherty & Burgess, 2009). The complex and longitudinal nature of biobank research means that there can be a disconnect between contributors and the research, and it is an area where deliberative techniques have been found to provide valuable insight (Secko et al, 2009). Such involvement activity is most obviously needed before beginning research; in the planning and prior to seeking ethical approval, but as many of these endeavours are longitudinal, it should also occur at various points along the research timeline - determined by the nature of the project and initial discussions. Practical and financial limitations must be taken into account, as well as the potential burden on those contributing to the PIE. However, this is not a reason to disregard in-depth involvement or deliberative methods in particular, rather motivation to seek innovative methods that support ethical research and ethical engagement. We might describe the participants' level of engagement on a sliding scale with governance and be open to the picture being different depending on appropriate methods. Certainly, being open to differing ideas and ways of contributing is important in involving people rather than simply consulting them, and this means treating people equally in epistemic as well as more obvious ways.

Engaging in reasoning that is non-adversarial and aims at epistemic equality while moving towards recommendations or principles for a research project can have direct benefits for research but also for the participants, including ethics and research literacy, empowerment and a sense of contribution (Elstub & Escobar, 2020). Longino states that "the social position or economic power of an individual or group in a community ought not determine who or

what perspectives are taken seriously in that community" (2002:131). In practical terms this may mean giving preference as much as possible to research programs with flat rather than hierarchical power relations, inclusive of participants. We might include conditions such as researchers should not be required to have specialized skills, beyond those needed for successfully carrying out their research, to avoid gatekeeping and specifically the exclusion of those able to contribute but who cannot meet such requirements, in addition to specialized expertise. This flattening and expansion of who is considered a 'researcher' is just one aspect of epistemic equality applicable to the development of ethical governance for biobank research but an important one for this thesis as a means to include e.g., athletes in policymaking for ADAMS. Beyond the category of researcher to those who engage with or co-construct research in other ways, the legitimacy of contributions and the weight they hold ought not to be grounded in who the person is but in what they offer, assessed on inclusive terms (Catala, 2015; Fricker, 2007; Miller & Pinto, 2013)

The value gained from taking part in deliberation is often described by means of contribution to societal (or group) goods, however there are individual benefits) and these may be more pronounced in contexts where there has been little previous involvement, such as WADA and differently, in situations of crisis or increased disempowerment such as during the COVID19 pandemic (Elstub et al, 2021).

One of the key epistemic merits of deliberation is that it can tell us where and why people disagree. Aiming for consensus is not necessarily the point (though aiming for some kind of co-existence and tolerance between conflicting views can be). A pluralistic approach allows space for differing views while working towards the same goal, for example of developing governance for a research endeavour. Recognition of difference, which may be conflicting, is important for its own sake, for example tolerance and respect for others. However, it also has instrumental value as a means to draw out the 'hard problems' in discussion of public interest and proposed research actions. In the case of WADA-ADAMS, this is the potential secondary uses and third-party access to ADAMS data for anti-doping and broader biomedical research uses. By focusing on the less malleable differences between people it may be possible to work with a deeper understanding of why those differences exist and how they inform relationships within the group taking part in the engagement; between the public, researchers

and research more broadly. Such understanding can be used to design both research and further engagements.

In working towards consensus, it is a well acknowledged fact that stronger or more voices may drown out the smaller ones. Therefore, we should protect or create spaces for n=1(a single, dissenting voice) to work in expansive ways that include all viewpoints that are relevant to the production of ethical governance frameworks, without simply pandering to preference (Sheehan et al, 2019).

PIE does not remove the need for field-specific expertise, nor does it pander to popular opinion, an accusation that has understandably been made, but can be addressed by ensuring that involvement and engagement is purposeful, appropriate (Solomon & Abelson, 2012) and based in reasoning and ethical grounding. This is of particular import for the types of complex questions raised by secondary uses of ADAMS data, inclusive and deliberative in method It is not the case that involving the public or interest groups implies that Follows is not required, but that different kinds of expertise should be better acknowledged and included than has historically been the case. In the WADA-ADAMS context the obvious example is the expertise of athletes who are required to operate within the anti-doping regulations and restrictions and whose data and samples are the potential research resource.

Reference to different forms of expertise is seen in the discussion of e.g., economically and racially marginalized populations or groups. As discussed in Chapter 6, biomedical and data-based research more generally has a diversity problem across a range of characteristics and contexts. One way of beginning to improve this is by finding more appropriate and inclusive methods of involving public(s) from the outset. One of the justifiable criticisms of public involvement, particularly when conducted for a specific ethical purpose e.g. deciding norms for potential data uses, is that it can replicate and reinforce existing inequalities. Avoiding this and facilitating involvement with those less often heard requires potential discomfort and critical work on the part of organizing parties, which can, but should not, be a barrier. PIE should be embedded where appropriate and not done disingenuously, to tick boxes. Engagement without clear purpose and willing receptors can be counterproductive and even harmful. When seeking input, researchers need to be clear about the potential applications and limitations of applying that input. For example, if asking people to consider what they think are acceptable uses of their health data being linked to aeroplane manifests to surveil for infectious diseases but that linkage is not possible, or work has already been approved and

it is not made transparent that has been done, then there are clear issues relating to integrity and trust, not least of which is wasting people's time and effort. Another example of this is asking people to do a piece of work and then disregarding the results because they do not confirm an assumption or affirm a pre-existing choice made by researchers or funders. Public involvement is not a replacement for good governance or REC oversight. It does not absolve poor practice in other areas of research and must go hand in hand with trustworthiness and a reasonable expectation of transparency. These ethical and operational requirements may be magnified in the case of population research that is conducted at a distance from contributors, for example the reuse of data or samples collected for clinical or anti-doping purposes; the linkage and aggregation of previously separate data sets. The particular ethical and PIE challenges of population research are discussed below.

7.4 Population research and representation

Population scale research where consent is not required needs to be transparent about broadly who and how participants or data contributors are enrolled in studies. Where data are anonymized, the characteristics that are known, for example demographics, should be made publicly accessible as well as the findings. In the US, for example, there is an overrepresentation of African Americans in non-consented studies, as compared with a) the population and b) studies requiring consent (where disproportionately fewer Black contributors compared with the population). It is not necessarily the case that there is deliberate corrective weighting occurring, but large medical centres that tend to be hubs for enrolling onto research or sites of data and sample collection are often in predominantly African American populated areas (Wilson et al, 2014). There is potential for a coercive or at least strongly influencing element, such as a lack of other options for treatment and conflation of research and therapy, along with a lack of evaluation of project information quality and lower levels of involvement of citizens in the design and governance of research. This is relevant to biomedical research practices in general and to the very diverse, global population of athletes whose data are managed in ADAMS.

One of the reasons underrepresentation of certain groups occurs because research is disproportionately located in High income Countries (HICs) with majority White populations and recruitment is not approached with structural inequalities sufficiently prioritized (Tindana et al, 2007). The sharing of results and related data has historically taken place via pay-walled HIC based journals that publish in English, thereby excluding those working in other languages, those outside of institutions as well as those in lower resource settings. Not

only are there multiple financial barriers, but the culture of research is such that HIC funded, focused and published work has been deemed more prestigious. Work conducted by or on behalf on HIC organizations and funders in under-resourced populations has produced models or interventions that are not accessible to the populations in which the research was conducted (Tindana et al, 2007; Bull et al, 2014) (this can also be seen in the Global North, for deprived or marginalized sections of high-income societies). Additionally, the focus of some studies conducted in Lower and Middle Income Countries (LMIC)s has been for diseases more prevalent in HICs, for example those into cancers and degenerative conditions such as Multiple Sclerosis and Alzheimer's, meaning not only could populations not afford to access the benefits or even the research outputs where paywalled in academic journals, but in some cases the particular disease or condition is not a priority for that community and there is little conceivable local benefit .

A research area known to experience these challenges is genomic and health-related population data, with repositories and cohort studies significantly lacking in ethnicities other than White European origins. Conversely, where global majority data is collected or accessed, some populations may be due to their 'scarcity'. Therefore, comprehensive understanding the range of factors affecting health is possible from a number of sources of data for White populations, but far less so for those from global majority populations, who may be minorities and also racially and/or economically marginalized in e.g. Europe and North America. It is important to be clear about the purpose of engaging with under-represented populations. The disparities in research cohorts are not the responsibility of individuals or community groups but need to be addressed at institutional and national levels in order to demonstrate trustworthiness and to increase the quality of population research. Increased engagement has been shown to facilitate greater participation but should be done alongside institutional improvements for example increased prioritisation and funding of iterative, embedded ethical assessment and governance development, intersectional thinking and significant public and interest group involvement. This may be particularly the case for data-focused research where often consent is not required by regulation for example due to anonymization, and therefore participation does not occur in the same way as for clinical trials, or biobank research that uses human-derived samples as well as data.

Under-representation of population groups in research may not seem directly relevant to a discussion of PIE and population scale research, however it offers examples of the multi-layered nature of exclusion in research and the importance of meaningful engagement with

people in their own contexts. Additionally, the ADAMS database is highly heterogeneous across a number of characteristics, including ethnicity and geography in comparison to other large repositories. For these reasons, claims of public health as a rationale for anti-doping measures, in addition to the values outlined in the Code and other key documents, Integrity, Openness and Excellence (WADA, 2021) should be at the forefront of thinking about what should be allowed to be done with athlete data and how to operate ethically. Some of the issues raised here may also be deemed the concern of the researchers and funders, and therefore where those parties are external or 'third party' to WADA may be seen as a separate concern. These challenges and how they relate to potential research use of ADAMS data are discussed more fully in Chapter 6. If secondary uses of ADAMS data were to be allowed and consent no longer required, then engagement could offer insight into how that ought to be set up and governed, increase research literacy and demonstrate trustworthiness from WADA and research partners. This raises a question of the rights and responsibilities owed by WADA to data contributors (athletes) regarding research access and the relationship between external parties and WADA. For example, how far might WADA's duties reasonably extend with regard to the conduct of a third-party using athlete data for biomedical research? This is an example of the kind of question that deliberative and ongoing engagement with athletes might seek to answer for anti-doping and for wider biomedical research uses. The latter category might also involve publics outside of the athlete community.

The risks of not engaging well with the public and stakeholders include a lack of understanding of risks and benefits of research participation or data contribution for participants, interest groups, e.g. patients, and for society as a whole. Research literacy may not be the primary aim of involvement for a given project, but might be a valuable additional benefit to participants. Though it is important to remember that any benefits to research are potential until the research has been conducted, knowledge will still be created, under the presumption that it will ideally be applied in some beneficial way. This isn't to suggest that there is always a single endpoint, especially for research that relies on data linkage or other techniques that mean data can continue to 'live' beyond the initial reason for which they are collected. The idea of the 'end point' in data-based population research is an interesting one, but outside of the current discussion. Having considered the risks and benefits of PIE in health-related research generally, we now turn to the specifics of WADA-ADAMS and

engaging with athletes as stakeholders in anti-doping and potential broader research uses of their data.

7.5 WADA athlete engagement

WADA has previously been criticized by athletes and commentators for their lack of transparency and exclusion of athletes from policy and decision-making processes (Dresikamper et al, 2016). This lack of inclusion and information sharing seems all the more indefensible given that 'Athletes are the most important stakeholders (in anti-doping) but the least heard' (WADA Athlete Committee, personal communication, January 2021). Recent efforts to address this include the reworking of the Athlete Committee and a working group on representation for athletes within WADA, supported by the Athletes Anti-Doping Rights Act (WADA, 2020). The WADA Athlete Committee (AC) first met in 2005 and in 2014 added International Olympic Committee AC members and has undergone review since, with a view to increasing their ability to represent athletes and be heard. Following the WADA governance review in 2018 which found that the AC offered more of an expert than broadly representative pool of athletes, a working group was set up in order to determine and then support 'the best possible representation of athletes' and this work is ongoing at the time of writing. Athletes in this context include professional and amateur, and parameters for inclusion have been set out along protected characteristics and geographic diversity. Models for a reformed AC have been proposed and work is ongoing to disseminate information about the models and support discussion and input. The AC is currently advisory-only and there are no athletes on either the Foundation Board or the Executive Committee of WADA (50-50 Sporting organizations and public authorities). Therefore, the model for the revised AC will have to be approved by those decision makers. Athlete representation on the decision-making bodies of WADA is a medium-long term aim for the process outlined above.

Any involvement of athletes in decisions around data uses should be coordinated with existing and incoming athlete representation bodies. However, it may be advisable to facilitate discussions and work towards production of outputs for example, drafting principles for allowing third party access to ADAMS data, using external independent facilitators and expert input. This is a commonly used method due to the value placed on impartiality and epistemic balance generally but is of particular importance where there is an historic low-trust problem such as between athletes and WADA (Gleaves et al, 2019). In the case of athletes and the WADA-ADAMS data, there is a question surrounding the quality of consent

(See Chapter 4) and therefore we must be especially clear about the relationship between recruitment and PIE and consent in the context of research access to ADAMS.

7.6 Consent and PIE

Public engagement is not a replacement for good quality consent procedures, where individual consent is deemed the most appropriate gateway, but can be utilized to develop and improve consent processes. PIE contributes to the improvement of consent by gaining deeper understanding of what is acceptable to publics and by increasing research literacy as part of the process. It is important not to confuse education and dissemination with dialogic and deliberative practices that seek to understand and apply public reasoning to a problem or context. It is necessary to be clear from the outset about the aims of a particular set of engagement practices, whilst remaining reflexive and able to respond to needs as they arise. A key aspect of this clarity, that is fundamental to good quality involvement and to ensuring that people understand and can give their valid consent to participate is whether the work is intended to be decisional or advisory and for what purposes. There may be an assumption that simply by engaging in the activity, recommendations will be taken forward, when in reality it can be very difficult to get buy-in from e.g., local authorities, research funders. The distinction between decisional and advisory matters because it may inform the decision someone makes to participate, especially on sensitive or controversial topics and/or in situations of power imbalance between the participants and the groups or organizations being discussed (Elstub et al, 2021). It also matters for reasons of fairness and informedness. This is highlighted in a context such as WADA due to the mandatory nature of anti-doping activity and the associated power relations between athletes and the organization(s). Engaging with stakeholders, in particular with athletes, regarding the governance and other aspects of research design may serve to empower participants and support greater understanding of research uses of athlete data. Increased information and involvement may lead to changes in consent to research and this should be accepted as part of a suite of moves towards greater transparency and valid consent. Where athletes are involved in meaningful ways and are able to see potential benefits from research, it may be that there is no reduction in the number of those that choose to consent to research uses of their data, but it remains important to gauge changes and to address any issues that arise as relationships and engagement develop over time and across geographies.

PIE can be related to consent in a number of ways. These include engagement around what type of consent is acceptable (within legal requirements) and what the boundaries are,

including how often and on what grounds to recontact for example. around permitting secondary uses of data or samples, such as in the ADAMS context; engaging with athletes to understand what they consider to be acceptable expanded uses of their materials and data, including how access and other research activity should be governed. This should take place prior to negotiating operational procedures with partners. Ethical literacy and research literacy may be explicit aims or ancillary benefits achieved through the engagement, and deliberative discussion and learning should be ongoing aspects of such an approach. This would potentially synchronize with existing efforts in ethics and anti-doping education which are recognized as important aspects of WAD-led harmonized anti-doping efforts.

PIE is often discussed in the same conversation as inclusion, equity and equality and they are intimately linked. This does not mean that involvement automatically mitigates the power disparities discussed above and therefore always leads to a more egalitarian approach. Without careful design and facilitation, replication of existing inequalities and power dynamics is a real risk, with potential adverse consequences for participants and for research (Elstub et al, 2021). Lack of transparency and engagement or involvement is problematic but poor or harmful practices in the attempt to include PIE also potentially threatens trust in research; therefore impacting the quality of research and the products that follow from that research. Context-specific understanding of who is meant by the public and who is missing, is vital in combination with involvement activity that is for and with participants, rather than 'done to'. This distinction matters for reasons of respect, integrity and trustworthiness for all populations, but is highlighted when seeking to engage populations or groups that have experience of historically being excluded from decisions made about them. Patient groups are an obvious example of the latter, who may also be the former, as are athletes subject to doping controls. It is important for both ethical and research quality reasons that we work with the public, stakeholders and interest groups in intersectional ways. There should be acknowledgement and support for the range of social and political, cultural identities a person may inhabit, how they overlap and inform their experience of the world. Encouraging constructive relationships that foster trust and openness in involvement is both the morally correct thing to do, and may be more productive in terms of the involvement supporting research progress. Care must be taken not to conflate involvement with recruitment or other research agenda that risk exploiting those taking part in research and/or involved in engagement. Being clear about aims and the justification of timing as well as content of activity is good practice in general and particularly important where there is a risk of

canvassing or recruitment rather than more meaningful engagement. Avoiding the introduction of community engagement solely at recruitment stage without ongoing input or clear indication of intent will also help. Identifying relevant groups and beginning to engage early and on their terms –as far as is practical-can help empower those taking part and may provide greater opportunities for participants to benefit from their taking part. The detail of how this can be achieved will differ by population, but taking elite athletes as an example, initial and intersectional work to understand their lived experience, factors that support and challenge their sporting life, their comprehension and awareness of research uses of the data and samples they are obligated to provide. To engage on their terms will require understanding how research and engagement is perceived and through utilization of methods that reduce the burden on athletes as far as possible; meeting people where they would normally go- training ground or gym for example, rather than requiring them to attend e.g. a university campus in order to participate. NADOs and other providers already mandate education modules around e.g. registered pool membership, Whereabouts and associated interaction with the ADAMS database. This well-established programme and network of people offers an opportunity to develop involvement using pre-existing resources which may reduce costs but as importantly, reduce barriers by reason of familiarity (noting that this is likely the case so long as the familiarity is positive).

Whether linked with education activity, or a standalone exercise, evaluation is needed in order to understand their effectiveness and take forward lessons from the wide range of involvement and engagement activities. Evaluating involvement can be challenging but it is necessary for a range of reasons, explored below.

Evaluation

Evaluation of PIE is a growing area of focus, reflecting recognition of the importance of meaningful involvement of populations in research, the increased demand by funders to include engagement and therefore the need to evidence its effectiveness. Outcomes may be measured in a range of ways. A methodological overview is outside the scope of this work, but can broadly be divided into quantitative, qualitative or mixed methods of evaluation (Grant & Booth, 2009). Evaluation of deliberative discussion, for example, has traditionally been conducted using discourse quality frameworks that apply statistical methods to the quality of the discussions and examine how effectively people move towards consensus on a particular point (Elstub et al, 2021). Qualitative or narrative approaches have been applied to examine content, tone and other more nuanced aspects of interactions (Elstub et al, 2021). In

evaluating PIE in research the primary focus tends to be on the participants' contributions and the process, however it is useful to capture those who engaged and those who see the engagement. This may be achieved through media representation, about the process and about the research which was the subject of the engagement. Learning from participants about what was successful for them, as well as what impact their involvement had on the research, can be applied to the design of future work and also used to evidence the need for involvement. Identifying those aspects that were 'unsuccessful e.g. participants did not engage; no or negative impact is also an important part of the iterative development of PIE for research with population biobank data.

Attribution of effects from involvement is difficult and there is debate about both how and what would be evaluated in a deliberation. The target of evaluation will differ somewhat depending on the topic being deliberated, but in deliberating ethical considerations for research we might assess e.g., engagement with moral concepts (Abma, Molewijk, & Widdershoven, 2009). Evaluation of process components, including for example whether participants feel heard; whether a range of diverse views supported, may be easier than evaluating the outcomes of involvement as they are not always neat or tangible and therefore can be challenging to assess in meaningful ways. One approach might be to find the target groups on whose behalf deliberations took place, and ask for their assessments of the value of the process and the outputs of deliberation, in addition to evaluation with participants, noting that this may not always be applicable or appropriate and being sensitive to making further demands, in particular on overburdened or over researched populations. In the anti-doping context this would be athletes whose data are in ADAMS, in the first instance. Deliberations and other forms of dialogic and iterative involvement tend to be highly valued but often for somewhat intangible reasons. For example, policy makers may have more confidence in the public's ability to contribute to decision making or policy development after observing a deliberation (Elstub & Escobar, 2020). Recommendations from groups of the public may more clearly articulate ideas or reasons that policy receptors (or researchers) thought may be of significance to people but lacked evidence for.

There are practical limitations to evaluation of PIE and deliberation in particular, for example transcription creates a separate entity from the visual or voice recordings that may be taken with permission of contributors - no capture of the subtleties, body language, group dynamic. Alternative capture methods are available, perhaps less commonly implemented, and deciding on appropriate methods of evaluation should be part of designing engagement

within research. Embedding context-specific knowledge has practical benefits for research and engagement design but it can also serve to support greater epistemic equality and justice and to reduce power imbalance more generally.

Epistemological balance and context matter for involvement in research: Polarization is a risk where very different views coincide and careful facilitation that supports equitable contribution and justification of views is needed to mitigate that risk. Another concern is dominance and deferral as a pair of symbiotic behaviours which can lead to agreement or consensus due to dynamics rather than facts (Elstub et al, 2021). Awareness of power relationships between stakeholders and proactive management of interactions during engagement activity, whilst allowing space for free exchanges, are some of the measures that can help to minimize this in the recommendations made here. Skilled facilitation and practical actions such as the design of the space in which interactions will take place can mitigate these challenges but will not remove them entirely.

7.7 Conclusion

Public involvement is not a replacement for careful ethical work but should be a part of it in the context of population scale research. Public interest is not a static or uncontested concept, the makeup of 'the public' shifts and the ways in which research is conducted with, by and for the public must also evolve. Defining the role of expertise, governance and of the potential benefits of involving publics in design and governance of biomedical research from short consultations to ongoing deliberative processes and co-production, may increase understanding of what is and is not acceptable to publics, and on what basis, while supporting trust and trustworthiness. For international population scale biobanks, deliberative and other methods are valuable, but should be focused on governance and advising on acceptability of broad research areas rather than to determine specific uses (Sheehan et al, 2019; Erikainen et al, 2021).

This is not a call for PIE in all settings nor a claim that such activities can 'fix' complex challenges in research involving humans. By examining the ways in which deeper and more meaningful, focused involvement of stakeholders including athletes, with regard to uses of data in ADAMS, in considered ways we can work to maximize the knowledge gain from contributed data and samples and the benefits of research for participants and future populations. Sharing learning from iterative engagement practices between projects and at organization level, across consortia ought to be standard practice and one way to encourage

this would be to mandate ‘open engagement’ in a similar way to ‘open data’. With locally informed adaptations and accommodations for those that need increased protections for example to remain anonymous. At the same time, we must be working to minimize harms and providing space for the expression of disagreement- with transparent routes for acting to implement change where needed. In addition to the ethical basis for involving populations in research that is about and for them i.e. that to do otherwise would be unjustifiable paternalism, and contra to the public interest justification that underpins most population research, there are significant potential benefits to engaging with publics’ modes of thinking and approaches. These can be both sophisticated and creative, potentially pointing to new research questions or methods of involvement that may not have been arrived at by (external) researchers alone.

Some corrective weighting of cohorts in PIE may be useful in order to redress inequalities rather than replicate them, though it is just one approach to a complex challenge. Need and inequalities will need to be considered based on those known to exist in society, and those specific to the context. Intended beneficiaries should be able to participate (e.g. people with additional needs or low incomes may face practical barriers to participation). Involving publics in the design of PIE both on a macroscale and per project is advisable. Commissioning ‘engagement’ that is imposed upon e.g. athletes without meaningful inclusion of their needs and priorities can be counterproductive, potentially exacerbating mistrust and wasting limited resources. It is important to be clear about when PIE is advisory and when it has decisional power. For example, in deliberation, more is not always better: methods must be chosen for their appropriateness and practicality as well as for sound ethical reasons. Therefore, work on clarifying the scope, aims and limitations of involvement should be carried prior to commencement of activity and reviewed as necessary throughout the process.

Ethics and PIE should not be conflated. Establishing preference is not the same as ethical deliberation. (Sheehan et al, 2019). Public involvement can be valuable and worthwhile for the range of reasons discussed in this chapter, but is not a panacea for poor design or governance by researchers and institutions. Timing is important- funded projects are often conducted on a tight timescale that has been set out in order to gain that funding and therefore involvement, where possible, should be planned with the relevant stakeholders and/or public prior to work commencing. Thus, one of the aims of this thesis is to examine crucial concepts

and methods for involvement that contributes to the conditions necessary for ethically justifiable uses of ADAMS data.

8 Conclusion and recommendations

Population research is justified based on 'Public interest' and biobanking is a critical component of population research. Public interest is neither a static nor uncontested concept, the makeup and interests of populations shift, therefore the ways in which research is conducted with, by and for the public must also evolve[32]. One innovation in research method that has grown at speed due to technological advances and increasing amounts of data being available is secondary research usage (including linkage) of existing datasets and biobank materials. This thesis has explored key ethical and governance issues associated with international population biobanking, with a focus on the WADA ADAMS biobank for athlete data relating to doping control. It interrogated specific challenges for potential research access to ADAMS and concludes by summarizing and then offering recommendations for further ethics research, and for WADA and other relevant actors to consider implementing before allowing research access to ADAMS.

ADAMS is a special biobank because the data and the samples from which some of the data are derived, have been collected and then retained as a central part of mandated doping controls. Research uses of samples and data have so far been limited to anti-doping, though this is already a broad and shifting term. The normative basis for sample and data collection, and for research into improving detection and other aspects of doping control is that doping is prohibited. There is almost universal agreement among nation-states that sport should be doping free (International Convention Against Doping in Sport, 2005). The normative justification for doping control itself is beyond the scope of this thesis but insofar as anti-doping is a legitimate realm of sport and requires a means by which test samples, results, associated data and other relevant information can be retained and managed, then ADAMS has a legitimate basis for its core functions. If the tool is essential to doping control, and doping control is legitimate, based on the almost universal ratification of the International Convention (191 states parties by 2021), then the core activities of ADAMS are justifiable on the same terms.

[32] P38 for an overview of public interest

If the normative basis of anti-doping extends to its necessary functions, it will therefore include anti-doping research using ADAMS, since its purpose aligns with the core activities and with the wider anti-doping movement. That said, secondary research uses of data beyond anti-doping do not have the same primary rationale or relationship to core anti-doping functions and thus justification for non-doping-related research is far from straightforward. This is tempered, however, by WADA's reference to public health as a justification for doping controls. If public health is a key justification for actions that may place burdens on those subject to anti-doping regulation, for example providing whereabouts information and random testing, then it may also serve as part of the justification for biomedical research uses of athlete data. The UN Convention on Doping in Sport places '…emphasis on the wider value of anti-doping efforts for protecting public health, sport integrity and values' (UNESCO, 2005). Potential public health benefits arising from research using ADAMS are not sufficient justification by themselves without accompanying work towards equitable benefit-sharing and a balance of interests between stakeholders that respects athlete choice without sacrificing potential societal benefits. Establishing policy and practices to support that balance should be done at the beginning of any agreement to allow third-party research access to ADAMS. A crucial part of that work will be engaging with athletes and other stakeholders.

Public involvement is not a replacement for careful ethical analysis but should form a part of a suite of activities that includes ethical oversight, gauging public acceptability, and creating good governance procedures in the context of population-scale research. Consent processes exist in part to respect individual choice and to protect parties by providing sufficient means of checking informedness and understanding (for specific informed consent, which is the closest model to the permission processes in doping controls). Nevertheless, the extent to which a person can be sufficiently informed regarding highly technical procedures, within a consent process, is limited. This may be particularly the case for large scale data-based research where in addition to complexity, the use of inductive methods, linkage and re-interrogation of datasets may mean it is not possible to 'fully inform' the person from whom consent is being sought. The challenge of uncertainty regarding uses and therefore the limits of specific informed consent require an adjusted approach [33]. Athletes being asked for consent to testing and to research are very likely to be focused on testing control purposes as

[33] See recommendations table S8.1

their right to refuse is very highly constrained, in addition to the fact that positive tests can have serious, even career-ending, consequences.

Defining the role of expertise, governance and the potential benefits of involving populations in the design and governance of biomedical research can provide clarity on the design of ethically justifiable research, beyond the minimum legal and professional requirements. Chapter 7 considered the range of possible approaches, from short consultations to ongoing deliberative processes and co-production, working with populations can increase understanding of what is and is not acceptable to those populations, and on what bases.

For international population-scale biobanks, there is a need for appropriately acknowledged expertise and representation of the pertinent communities and populations. In particular, deliberative engagement and other methods of meaningful involvement are needed for population research using biobanks in general and for ADAMS, because of the complexity of the issues underpinning consent. The aim is not simply to seek opinion, but to support reasoned discussion that feeds into decision-making and policy development. For that to be effective, there must be agreement from stakeholder, specifically WADA in this case, that findings will be incorporated into governance or policy. Where that is not the case, there is a risk that engagement may not simply be ineffective but can be counterproductive. Public input ranges from strong negative opinion to un-informed to 'lay expert' and care must be taken to ensure that a range of voices and standpoints are heard and given appropriate weight.

Differing experiences, and kinds of expertise[34], can provide insight into stakeholder expectations and potential challenges to the proposed research that can prevent problems

[34] Expertise is a descriptive term. A description of expertise requires an knowing what the expert knows and knows how to do. The knowledge and skills that make up expertise 'provide the potential for behaviour: that of an 'expert' in their particular topic or activity' and are, for the purposes of comprehending expertise, most usefully understood in terms of their effects or functions, rather than by their content.

Expertise is more than just acquiring the right knowledge and skills. It is a combination of those attributes with some natural aptitude, access to resources and the opportunity to practice the particular skill. This latter aspect is sometimes overlooked in favour of talent or natural ability (which are important, but without practice, insufficient for expertise as borne out in the sporting world where discipline and practice are key).
A general description of expertise is that 'it is proficiency and deep knowledge that is distinctively greater than the average person' (Baker & Farrow, 2015). Traditionally this type of definition has been used to describe for example academic or sports excellence, and it still applies to those but 'experiential expertise' is increasingly recognised as being of importance in deciding who may credibly contribute. For the discussion of WADA ADAMS research processes and the associated ethical challenges, the athletes who are experts in the world of elite sport, which includes being subject to doping control requirements, provide this kind of expertise. It should

before the start of an undertaking *and* provide guidance throughout. There must, however, be clarity about the reach and power of any involvement and continued communication throughout the work to prevent using public contributors, or athletes in the case of ADAMS, simply as a resource. One simple but important action is to share 'results' from a research endeavour with those who engaged as part of the process. This can be done in a number of ways, from simply sharing published work to having participants co-create outputs.

Athletes have considerable experience in being subject to anti-doping regulation and the activities that are mandated as result. They are also the originators of the data and samples and therefore the group at most risk from any harms that might arise from the use of those data. Athletes may stand to benefit the most from the ethical use of data for anti-doping research if it supports and protects 'clean sport' but will not necessarily gain from broader biomedical uses. Therefore, the distinction between anti-doping related research and biomedical research uses must be made as clear as possible. This should be done as part of the existing education modules that athletes are required to take part in and should be outlined in the consent process itself, with the caveat that athletes are already burdened with significant processes, time and informational commitments and therefore work is needed to establish what best practice will look like. Additionally, communicating changes such as these to every stakeholder or signatory organization that has an educational role will require considerable effort and resource. Smaller stakeholder organizations that may not be in a position to carry out research themselves should be supported in education, consent and governance endeavours: financial inequality should not be a barrier to the quality of consent or to ethical conduct. All of these measures aim to enable informed choice regarding broad research type, if not specific uses. This could be supported by introducing a consent process that allows contributors to permit anti-doping research, but not broader uses: a type of tiered consent. That process should also allow for the opposite choice: to allow biomedical research without anti-doping work, though this might present more of a challenge to the risk-benefit relationship and requires further investigation. The requirement to provide samples and information may be considered to be part of the 'contract' to take part in clean sport, however there are elements of the mandated doping control activity that challenge this idea.

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be noted that the specific kinds of expertise do not exclude each other. It is possible to hold more than one kind, as it is with other states and attributes.

Describing the relationship between athletes and anti-doping organisations as 'contractual' applies only in a somewhat extended sense. Athletes may receive support from national sport agencies and a condition may be written into their contract. It is not implausible to say that beyond professional sport, there will be many elite non-professional athletes or whom the 'contract' to train and compete clean, is almost symbolic. It is clear that there are unequal power dynamics and the mandatory nature of doping control for those who wish to compete at an elite level impacts the validity of consent. This kind of relationship and the associated rights, duties and ethical issues is not limited to the sporting world and therefore the considerations of power dynamics and epistemic inequalities, for example, in this thesis have wider application in thinking about population biobank and genomic research. As Baier states, 'Where one depends on another's good will, one is necessarily vulnerable to the limits of that good will. Trust then, on this first approximation, is accepted vulnerability to another's possible but not expected ill will (or lack of good will) toward one' (1986:235). When we trust someone or say that he someone is trustworthy, we implicitly mean that the probability that he will perform an action that is of benefit or at least not detrimental to the one trusting is high enough for us to consider engaging in some cooperation with him. (Gambetta, 1988 in McNamee, 1998). This becomes more difficult where parties are sufficiently unequal that vulnerability is entirely one-sided and more so where systems shore up those inequalities. This speaks to a range of ethical issues around voluntariness and coercion that are discussed in Chapter 6, in particular the ways in which the WADA-athlete dynamic affects consent and the justifiability of the actions that follow from consent under those circumstances.

There is a presently a lack of awareness regarding research uses and procedures in the athlete population (Athlete Committee, personal communication, January 2021) and therefore education will need to be a central part of any policy to allow the sharing of ADAMS resources for research beyond anti-doping. There is already an extensive anti-doping education programme (ADEL) and delivery networks that could be utilized to deliver education about research alongside existing content. Identifying knowledge gaps and areas of particular concern to athletes can be done through working with athlete representatives to develop the engagement recommended here. Making the best use of existing resources and networks is a cost-effective and practical approach and reduces the burden on athletes compared to introducing new or additional systems.

Such suggestions come with the obvious warning: ‘one size does not fit all’. Different methods of involvement and configurations of the public will be needed depending on the circumstances. Involvement activities cannot ‘fix’ complex challenges in research involving humans, however examining the ways in which deeper and more focused involvement of stakeholders can be incorporated in considered ways can maximize the benefit of research while minimizing harms. Where the risk of harms cannot be entirely removed, part of this work should include planning for mitigation and where appropriate, compensation.

Corrective weighting of cohorts in engagement to oversample for those groups which are proportionately less likely to participate e.g., carers, groups with historical research related abuses, may be useful in order to redress inequalities rather than replicate them. This must be done with care to avoid over burdening specific groups based on one characteristic. Specific needs and inequalities that impact a person’s ability to participate will need to be considered based on those known to exist in society, and particular to the context, for example provision of accessible materials, supporting digital access. Intended beneficiaries of research should be able to participate in related engagement and not be designed out of a process that speaks about them (e.g., people with additional needs, low incomes or without digital access may face practical barriers to participation). For athletes this might be seen in the differences between sports, nations and socio-economic groups within nations. With these thoughts in mind, we might ask what an inclusive ADAMS related policy for secondary use might look like. Inclusivity for ADAMS should be informed by engaging with a range of stakeholders, primarily athletes, and by reference to known inequalities and exclusions in the sporting, specifically doping control, context.

As discussed in Chapter 7, designing processes that better protect and empower contributors to research, requires an intersectional approach in order to respect the multiple identities that a person may inhabit. By understanding how characteristics intersect to increase or remove barriers to participation in both engagement and research processes, can be designed to be robustly inclusive. This is both ethically required, because to do otherwise would be unjustifiably paternalistic, not to say exploitative, and pragmatically important since better concordance is likely to have the effect of increasing participation both in absolute numbers and with respect to diversity across a range of characteristics.

While one can see how, for WADA, broad consent for the use of ADAMS data to be used for research would represent an efficient and self-interested model, they could also claim that they were following the general trend in biobanking for broad consent processes. The accreditation of researchers prior to allowing access, along with expectations of reporting and channels for disclosure of unethical conduct should support the research internally. It would be a significant undertaking for WADA to oversee all research projects and uses, and it may not be the best use of time and resources within current systems, however it is an aspect that WADA will need to consider and to justify the choices that are made. Decisions about access models and the scope and limitations of WADA and other stakeholder obligations should be made collaboratively, acknowledging that Where biomedical research uses outwith doping control, or sports, are being considered, WADA may not have total jurisdiction in the same way as for anti-doping There are several organizations that have effective data access, and third party uses policies in place, and it would behove WADA to learn from them in developing its own policies. Two differing but equally germane exemplars are the SAIL databank and the GA4GH work streams and framework (https://saildatabank.com and https://www.ga4gh.org).

Specific informed consent is unlikely to be viable due to the range of possible uses of ADAMS data and the potential for uncertainty around those uses at the time that initial consent is being sought. Dynamic consent is one model that seeks to address this challenge by returning to contributors for consent for each new use. As noted in Chapter 4, however, this can place undue informational and decisional burdens onto data contributors. Broad consent that acknowledges the limitations of informedness with respect to research uses and focuses on informedness with regard to procedures and governance may offer a way forward that respects autonomy, supports development of iterative governance and facilitates ethical research.

Whether for anti-doping research, or by extension to biomedical uses, adjustments and additions to the current WADA consent and governance process are required in order to create the conditions necessary for ethically justifiable research uses of ADAMS data. Revisions suggested in the thesis better protect the interests of the athlete participants than current systems and propose measures to create necessary conditions for novel research uses of ADAMS beyond anti-doping. In order to protect the interests of athletes and to better serve the principle of respect underpinning consent as laid out in Chapter 4, it is proposed, initially

at least, that there is a separation of consent to testing from consent to research, followed up with engagement with athletes on their attitudes to data usage and the acceptability of proposed strategies, designed with athlete input using an iterative process.

Adopting a graded approach to this matter should also deliver on claims to legitimacy and trust as discussed in chapters 4 and 6. This will also be an opportunity for WADA and associated organizations to demonstrate trustworthiness by co-creating policy and governance with the data contributors (athletes) themselves. Trustworthiness is important for constructive ongoing relationships between organizations and data contributors. Trust is particularly vital where processes are not entirely transparent, or it would be an unreasonable amount of work for contributors to know all of them and therefore they need to be able to trust what they are told. Improved transparency should be worked towards concurrently with improving the trust between athletes and WADA (the latter as a proxy for those parties allowed research access), contributors and researchers. Trust is also important due to the sensitive nature of the data held in ADAMS, for example hormone and steroid levels, prohibited substance test results and due to the length of time that data are held (up to ten years, with retrospective testing allowed). Where data are anonymized, or there is out-of-date contact information, it may not always be possible to contact contributors to gain their permission to share and therefore there needs to be clarity from WADA regarding what will be done with that data. Those decisions ought to be made involving athletes, as the primary interested population.

Involving populations in the design of PIE both on a macro scale and per project is advisable because it better protects the interests of those populations compared to non-involvement and empowers them to make decisions about their contribution to research and input into the design and governance of research where appropriate. Commissioning ‘engagement’ that is conducted at rather than with and by e.g., athletes as passive recipients rather than empowered actors can be counterproductive, potentially exacerbating mistrust and wasting limited resources. It is also important to be clear about when public involvement is advisory and when it has decisional power. For example, in deliberation more is not always more: methods must be chosen for their suitability to context and for practicality as well as for sound ethical reasons. Such an approach could be invaluable in enabling athletes to co-create policy for sharing ADAMS data with researchers. Facilitating deliberations with athletes and relevant stakeholders to establish the boundaries of what is acceptable, and to understand the bases for that, must be done with agreement from key stakeholders e.g., WADA to

implement recommendations and provide reasons for rejection where appropriate. Ethics and PIE should not be conflated. Establishing preference is not the same as deliberation and involvement must take place in combination with reflexive governance and appropriate ethical oversight.

Clarifying harmonization and differentiating it from standardization provides an enriched conceptual foundation to support work harmonizing anti-doping and research governance, including means of seeking consent. Applying a broad consent model that allows for a clearly delimited and limited right to withdraw, in conjunction with reflexive governance and ongoing ethical oversight and channels for stakeholder input will provide conditions necessary for WADA to ethically justify commencing extended research uses of athlete data. To quote Townend with a statement that speaks to the heart of this thesis and the accompanying recommendations for WADA: 'Harmonization is possible, but it will not be found through a top-down harmonization of national legislation, it will come from a bottom-up harmonization of researcher practice and public acceptance' (2018: 657).
Central to the thesis is the examination of existing governance and ethics processes relating to the uses of athlete data in ADAMS concomitant with seeking conceptual clarity for crucial aspect of those processes, specifically harmonization. This was done with the aim of recommending moves towards ethical best practice for current and potential secondary uses of those data. A summary of recommendations for action follows this chapter. It outlines actions, target actors and provides aims and rationale for each recommendation. They are intended to be of practical application for WADA and other relevant parties in the development of policy and processes for the ethical governance and use of WADA ADAMS data for anti-doping and for wider biomedical research uses.

8.1 Summary of Recommendations

	Recommendation	Target actor	Aim	Supporting Notes
1.	Clarification of the Public Health claims in the World Anti-Doping Code	WADA External expert input (Public Health)	If the justification for doping control is linked sufficiently well to Public Health, then it may extend (with supplementary work/justification) to anti-doping research and provide the foundation for biomedical uses of the data	
2.	Gauging stakeholder acceptability of the potential research uses of ADAMS data	WADA Athlete organizations	1. To understand the current levels of awareness around ADAMS data and 2. Gauge understanding and objections to research uses of data (beyond doping).	In the first instance this should be athletes whose data are in ADAMS, expanding to include other stakeholders and potentially some external public input.
3.	Creating and monitoring ethical governance procedures in the context of population-scale research	WADA Third-party researchers Funders	Prior to allowing research access to ADAMS, an iterative process of governance and ethics development should be undertaken to include stakeholders, in particular athletes and	
4.	Clarity regarding the distinction between 1. anti-doping research and 2. Biomedical research unrelated to doping	WADA Research community		Processes should allow athletes to choose anti-doping research only, or both types (with stated parameters around biomedical uses)

5.	Use of existing education modules and delivery network to provide information about research to athletes and support informed consent (as the current model).	WADA, ADOs Athlete organizations	Raise awareness of current and prospective uses of data.	This could lead to an increase in refusal to consent, however that is not a justification against improving access to information. If consent is not the basis on which research uses are allowed then the informational aspect remains important.
6.	Stakeholder involvement in policymaking	Athlete organizations; ADOs; WADA	Increase inclusivity and the range of voices that contribute to decision-making about data governance and the potential access to data by external parties.	
7.	Investigation of consent processes	Independent ethics experts; WADA; athletes.	To examine current processes for viability and ethical justification and to make recommendations for improvements where needed.	
7.1	The limits of specific informed consent require an adjusted approach for consent to research uses of ADAMS data	Independent ethics experts; WADA	To investigate the best model of consent to third party uses of ADAMS data. Informed by work on whether individual consent is the appropriate basis for research permission.	Adjusted so that, for example, informedness comes from governance structures rather than solely the specifics of research uses. Also adjusted in terms of moving away from specific informed consent as the default. Broad Consent may be common in biobanking but the public understanding of the differences between models and the relevant justifications is limited (this can be supported

				using the education programme and involving stakeholders in deliberative discussions to inform policy, governance)
7.2	Tiered (broad) consent model suggested to allow for choices reflecting biomedical and anti-doping research uses.	WADA External ethics advisory	In order to retain a consent process (while undertaking work to examine alternative ethical solutions) that is valid and fit for the specific context.	
7.	Separation of consent to testing from consent to research- form and timing and education sessions should be different	WADA ADOs	To reduce conflation of research with testing for athletes and therefore improve consent processes. Needs to be in tandem with increased transparency, involvement and education.	Education around consent could be shared so long as made clear that the two applications are separate and that I can refuse one and consent to the other without consequences (adverse cons for my sporting career)
8.	Further work is needed to investigate the ethical challenges arising from the possible (athlete) choice to allow biomedical research only	External ethics advisory WADA funded research		Risk-benefit Informedness Results reporting Familial impact (chromosomal testing; genomic data)
9.	Planning for mitigation of harms and, where appropriate, compensation.	WADA Third party research organizations Funders	To minimize risks from research uses of data, but recognize that people may be more or less vulnerable sue to a range of factors. To acknowledge that zero risk	Funding and infrastructure also needed. Limited application where data anonymized

			is not possible and plan accordingly.	
10.	An explicitly intersectional approach to involvement and engagement, ethics and policy	WADA- updates to policy Expert oversight to ensure intersectional and inclusive approaches Athlete organizations	To demonstrate trustworthiness through greater understanding and inclusion of underserved groups. To recognize and respect the diversity of the global athlete population and work with a plurality of values and experience to design policy and systems.	Needs expert input to support co-creation with athletes Investing in building a strong foundation for intersectionality to embedded in policies and procedures is justified on ethical and pragmatic grounds.
11.	Development of accreditation for external researchers	WADA Funders Research organizations	Assure research ethics norms are upheld and enable high quality research in the public interest.	GA4GH or SAIL systems as exemplars. Both criteria and process should be inclusive and transparent. Extra support should be provided to facilitate research access for lower-resourced parties.
10.	Increase transparency of processes and policies- make available on the WADA and other relevant websites but also by including stakeholders in design and dissemination.	WADA, Athlete organizations, ADOs	Transparency as an aspect of accountability and the demonstration of trustworthiness. Also, to increase informedness for consent decisions.	
	Make explicit when involvement has decisional power and when it is advisory-only. This should also include communicating outputs and impact with participants after they have taken part	WADA, Researchers, Funders to require through their policies	To ensure integrity and demonstrate trustworthiness. To respect the time and efforts of participants. To build trust relationships with stakeholders that enable meaningful involvement	

	Clarification of harmonization and standardization 1. Conceptually and 2. As they are used by the relevant agents (Primarily WADA in the case of ADAMS)	WADA with external expert input	Conceptual clarity is useful in policy and governance development, but it is also ethics-supporting.	Clarification of these terms, supported by the other recommendations, and in support of them has positive practical application for the developments of ethical research-supportive processes.

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