Australian Aboriginal and Torres Strait Islander collections of genetic heritage: The legal, ethical and practical considerations of a Dynamic Consent approach to decision making

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Abstract

Dynamic Consent (DC) is both a model and a specific web-based tool that enables clear, granular communication and recording of participant consent choices over time. The DC model enables individuals to know and to decide how personal research information is being used and provides a way in which to exercise legal rights provided in privacy and data protection law. The DC tool is flexible and responsive, enabling legal and ethical requirements in research data sharing to be met and for online health information to be

maintained. DC has been used in rare diseases and genomics, to enable people to control and express their preferences regarding their own data. However, DC has never been explored in relationship to historical collections of bioscientific and genetic heritage or to contexts involving Aboriginal and Torres Strait Islander people (First Peoples of Australia)..

In response to the growing interest by First Peoples throughout Australia in genetic and genomic research, and the increasing number of invitations from researchers to participate in community health and wellbeing projects, this article examines the legal and ethical attributes and challenges of DC in these contexts. It also explores opportunities for including First Peoples' cultural perspectives, governance and leadership as a method for defining (or redefining) DC on cultural terms that engage best practice research and data analysis as well as respect for meaningful and longitudinal individual and family participation.

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Introduction

Throughout Australia, museums and other medical and scientific research institutes have historically collected, and still hold, various types of heritage belonging to Aboriginal and Torres Strait Islander peoples (First Peoples of Australia). From earliest contact with Europeans, First Peoples' traditions of art making, ceremony, song, dance, language and ecological knowledge were removed and placed in collections that continue to be governed by western epistemologies, values and beliefs. First Peoples' skeletal and other bodily remains such as hair and blood were also commonly collected by colonial settlers and, in later years, social and scientific anthropologists. This collecting was carried out on a large scale and in most cases without what we would now consider to be appropriate methods of governance and consent. Such collections, their legal status and their future use in genomic research are the central subjects of this article.

Even with the historic removal of heritage materials from family and community lives, from a First Peoples' perspective, these significant collections that include bones, hair and blood represent traditions and ontological knowledge that are still passed down from one generation to the next. Protecting heritage materials has been, and always will be, paramount to the social function and survival of First Peoples' identity, as defined by family and community structures of kinship and their connections to significant places and ancestral lands. In a recent discussion paper, the Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS) reported that "[...] Indigenous knowledge provides the fundamental basis of connection to places and protecting, teaching and transmitting knowledge is in turn fundamental to maintaining cultural authority."¹ The protection of First Peoples' heritage and culture is also, as discussed further below, a human right.

The institutional preservation of First Peoples' cultural heritage raises legal and ethical questions in terms of ownership, ongoing custodianship, potential repatriation and free, prior and informed consent² for future research use across generations of family. The main aim of this article is to examine these questions from legal and normative perspectives. It focuses

particularly on the legal and ethical basis for culturally-appropriate and well-informed decision-making processes by First Peoples about legacy collections of biological samples, whether for retention, return to the donors or descendant family members, destruction, or further access to and research use of the samples. The article considers whether a Dynamic Consent (DC) approach³ might be adopted with cultural leadership to support communication, education, deliberation and flexible choices by First Peoples. It posits that the DC model can provide for autonomous and informed choice by donors and their descendants about the treatment of individual samples, cognizant of both the samples' value for future research and their profound personal and cultural meaning.

Collections of bodily materials in Australia – historical context

Globally, the collection of Indigenous bodily materials has been intrinsic to the colonial project. The objectives of such historical collection varied, but included, for example, posthumous retribution for the purported wrongs of a person or group⁴; as souvenir or curio⁵; for display; commercial trade; anatomical, anthropological and phrenological research⁶; and as trophies.⁷ Worldwide examples range from the collection of tattooed heads of Maori,⁸ to skeletal remains (especially crania) of First Peoples of Australia,⁹ Native Americans¹⁰ and the Saami of northern Norway.¹¹ From the early decades of the 20th century, in Australia and elsewhere, formal anthropological research activities included the collection of hair, blood, bone and other bodily materials from humans. The researchers also obtained people's detailed physical measurements, compiled genealogies, and photographed individuals and groups. These collections were sometimes joined with heritage materials held in museums, libraries and similar institutions. Within these institutions some of the bodily materials remain, while others are now missing, or have been destroyed.

Repatriation demands by Indigenous senior knowledge holders and community members intensified from the 1980s worldwide,¹² and efforts were made to take back significant heritage materials to family groups and communities. This occurred by means of consultation and agreement in some circumstances, whilst in others it was mandated by government policies and programs, court orders or legislation (such as the *Native American Graves Protection and Repatriation Act* (1990) in the USA). At the same time, discomfort about the retention and continued storage and use of First Peoples' bio-cultural heritage by institutions began to rise. In cases where these collections remained housed within museums, libraries

and universities, ethical concerns coupled with the vocal and powerful global Indigenous rights movement tended to act as a brake on research around the end of the 20th century. Attention turned away from outdated practices of accumulation and trade of samples towards eliciting individual, family and community perspectives and preferences about governance of the collections.

The current status of legacy sample collections

In recent decades, researchers representing diverse fields of social and medical inquiry, such as epigenetics, microbiomics and climatic adaptation, have been engaging with First Peoples in decisions about bio-scientific collecting, storage, governance and future use. Attention has also returned to those materials gathered in the past. In Australia, examples include two major institutions that hold collections of First Peoples' biological samples.

At the Australian National University (ANU), the National Centre for Indigenous Genomics (NCIG) is responsible for a collection of First Peoples' blood samples held at the John Curtin School of Medical Research. These samples were collected between the 1960s and 1990s from about 7000 First Peoples living in northern regions of Queensland and Western Australia as well as the Northern Territory.¹³ In 2012-13 a consultative committee with majority Indigenous representation was convened to assess the collection and determine its future. The committee decided that this collection should be retained and expanded under Indigenous custodianship, in recognition of its scientific, historic and cultural significance. The NCIG was established as a result.¹⁴ The NCIG also holds documents and metadata relating to the blood samples, including linguistic records, photographs, name lists and family trees.¹⁵ The NCIG's role is to protect and preserve its collection in accordance with international scientific and human rights standards as well as through strong community engagement strategies. The NCIG shares knowledge about the collection with sample donors (if still living) and their descendant families and respective communities. It promotes the collection's future through governance by a majority of First Peoples committee representatives.¹⁶

A second major legacy collection is the Aboriginal Heritage Project (AHP) located in South Australia. The AHP is a research collaboration between the Australian Centre for Ancient DNA (ACAD), the South Australian Museum, the NCIG, Deakin University and La Trobe

University. The AHP predominately includes hair samples obtained during expeditions carried out by Joseph Birdsell and Norman Tindale for the Board of Anthropological Research from the 1920s to the 1970s.¹⁷ About 6200 hair samples from more than 5000 people form the basis of the collection. Extensive consultation about the management and use of the samples has been required in order to generate (with cultural permissions) a map of the genetic diversity of the First Peoples of Australia.¹⁸ The NCIG and the AHP are significant in Australia in terms of their scale as well as in the approaches taken by their custodians. They both preserve First Peoples' bio-cultural heritage and the other associated data such as family histories and photographs, and make it available for new research uses, with clear policies and practices of community consultation.

The challenges raised by legacy sample collections

This article focuses on legacy collections of this type because of the challenges they raise in terms of identifying legal status, weighing scientific, cultural, family and personal values, ensuring ethical and consultative research practice and, ultimately, upholding the recognition and practice of First Peoples' human rights. Historical collections of blood, hair, bones and other material collected from the bodies of First Peoples of Australia are political spaces of competing values, requiring stakeholders to engage in a complex weighing up of priorities. For instance, the research institutions acting as custodians of such collections may attach great significance to best practice in ethical research conduct and community engagement and share or cede control over samples and data to donors, families and communities. Yet their activities and policies may also be motivated by an awareness of the value of this material for scientific research that could yield future health and cultural benefits to participant communities.

First Peoples have been significantly underrepresented in genomic research to date; an absence that may lead to deepening inequalities in the provision of healthcare to their communities over time. Since the completion of the Human Genome Project in 2003, interest in genomics research has continued to gain momentum. Many countries around the world are exploring genome sequencing, with increasing numbers of participants; examples include the 100,000 Genomes project in the United Kingdom; the Precision Medicine Initiative in the United States; and the Australian Genomics program. One of the major criticisms of such research is that despite purporting to be conducted on a 'population level' they are "failing on

diversity".¹⁹ In a review of 2,511 genome-wide association studies, including 35 million samples, 81% were found to be of European ancestry.²⁰ This is a troubling statistic if genomic research is to form the foundation for the future of precision medicine. It also poses a significant challenge to global health equity. If peoples, as diverse individuals and communities, are not represented within the research cohorts, the findings may be limited. This can lead to an inherent lack of applicability of forthcoming treatments and therapies, embedding system-wide inequalities that may take generations of research to remedy.

There have been explicit examples of research that aims to diversify the populations included. In 2016 for example, 23andMe received funding from the National Institutes of Health (US) to create a genetic resource for health research in African Americans, specifically to reduce health research disparities.²¹ The Human Genome Diversity Project, developed in 1991, was intended to research human genetic variation alongside the Human Genome Project, by gathering samples from Indigenous populations that might provide insight into how and when patterns of diversity were formed.²² Immediate responses to the latter project were heavily critical, with concerns raised about whether this so-called 'Vampire Project' would have benevolent outcomes, or whether it in fact was no more than "genetic colonisation".²³

These projects, and critical analysis of the research data, demonstrate the need to increase diverse representation within studies in order to address discrimination. A starting point is to find ways to enable participants to be inclusive partners rather than merely uninformed subjects within research endeavors, and to explore how research can progress in ways that are meaningful and culturally aligned with the values of participants, their families and wider communities. Yet institutional collection custodians may face divergent options; motivated to promote the research use of their collections in pursuit of equitable scientific and health goals, while concurrently seeking perhaps to restrict access, limit the scope of projects, and return or destroy samples in accordance with the preferences of the sample donors and their descendant families and communities. These options are neither straightforwardly dichotomous, nor fixed in time.

In addition, for institutions holding legacy collections there are practical challenges associated with identifying who has authority to make decisions about the samples and what decision-making and consent processes should be adopted. (As we indicate later, these challenges will not be solved simply by the introduction of a DC approach.) Legal questions

of ownership, access and use must be assessed. The possibility of returning historical blood, bone and hair samples to donors and communities has required scientific institutions to develop appropriate policies and cultural governance committees and frameworks. They must also meet the challenge of applying current ethics guidelines for the conduct of genetic and genomic research to old sample collections of perhaps unknown provenance, as well as adhering to guidelines for the conduct of research with First Peoples of Australia, and international instruments and norms. They must adopt effective mechanisms to establish and maintain communication with First Peoples about bodily material collections while recognising that individuals and groups will hold diverse and changeable opinions about genomic research. Culturally appropriate consultation and consent methods regarding future sample use, together with high-quality education resources, are all essential tools for collection custodians.

What follows is a comprehensive analysis of the complex legal and ethical frameworks overlaid with cultural and community values relevant to First Peoples' historical genomic materials. This analysis commences with the legal and regulatory framework applicable to historical biomaterial collections, addressing issues of ownership and access and future use. The application of Australian and international law is reviewed, together with guidelines for ethical research conduct and best practice recommendations for biological repositories. The role of First Peoples' governance of collections and ways to ensure that cultural perspectives remain central to decision making is also considered. Finally, the potential of a DC approach to enable individuals and communities to exercise their decisional power and influence in genomics research is reviewed. This analysis may be of interest to other collection holders considering modern uses of historical bio-scientific samples.

Legal and regulatory framework

The legal and regulatory framework relevant to historical collections of First Peoples' blood and hair samples is complex and its application is opaque. The circumstances of the collection process are an important factor in this analysis, with implications for legal ownership and ongoing ethical use, but these circumstances are often lost to history.²⁴ It is not always clear whether consent was given by people providing samples, or whether there was coercion or a sense of obligation to take part. Custodians of the ACAD sample collection in Adelaide have indicated that the process "might have more closely resembled a form of

‘implied’ consent or ‘compliance’...[I]n many collecting points, such as missions, Aboriginal people would have felt obliged to participate if the mission authorities directed them to.”²⁵

While it is possible that the samples were collected in accordance with scientific and ethical practices common to the period, by researchers acting in good faith, it is very unlikely that formal and freely-given ‘informed consent’ – as we would understand it today – was present.²⁶ In at least one more recent instance overseas, samples were collected ostensibly for one purpose but utilised for multiple other purposes without the knowledge or consent of the donors.²⁷ If samples were not lawfully obtained, it becomes more likely that strict legal ownership (as discussed below) would be attributed to the sample donors.

Current ownership of legacy samples

Institutions

The question of whether institutions holding legacy samples today have ownership of those samples cannot be answered with certainty. Australian legislation that applies to historical collections of blood and tissue samples rarely addresses this issue directly. At common law, it is accepted that there is no property in human bodies or body parts, although this rule rests on dubious legal authority and there are many exceptions.²⁸ One of these is the so-called "work or skill" exception that is enlivened when someone has "by the lawful exercise of work or skill so dealt with a human body or part of a human body is his lawful possession that it has acquired some attributes differentiating it from a mere corpse awaiting burial."²⁹ Under Australian common law, if the samples were lawfully obtained, institutions holding samples that they have preserved (exercised "work and skill" upon) could have a form of property right – a possessory interest – in those samples.³⁰ Blood samples preserved in freezers are likely to meet this "work and skill" exception; this includes, for example, the large starch-gel laboratory collection established by Professor Bob Kirk at the John Curtin School of Medical Research at the Australian National University, which was the basis for the NCIG. Hair samples, at least those taken from living people, are also capable of being property.³¹

The decision, then, as to whether the samples in question can be 'propertised' will likely turn on whether their collection itself was lawful. Before the introduction of the Human Tissue Acts in all Australian jurisdictions from the late 1970s onwards, the law was silent on the removal of human tissue for scientific purposes. Conceivably, the tort of battery could be

drawn into service in considering the legality of sample collection from living humans before this time. It is likely that the elements of battery (intention, voluntariness, and positive action resulting in contact with another person) could be made out. Thus, the analysis will turn on whether express or implied consent was freely given by the sample donor. As noted above, the circumstances of collection in many cases may be unclear, and so it would be difficult today to answer this question either way based on a broad assessment of collection practices.³² Individual institutions may be able to claim a defence of consent to an allegation of battery. It would be necessary to examine the specific details of individual sample holdings or even potentially individual samples.

If it is assumed that samples *were* in general obtained lawfully because they were given with express or implied consent, and if the "work or skill" exception is considered to apply, the institutions that now hold samples will have some property rights over them; at least, the right to retain possession.³³ These property rights would likely not extend to outright ownership.³⁴ It is unsettled whether the existence of institutional property rights over legacy samples creates corresponding property rights in the donor.³⁵

Donors

In addition to the above, it is difficult to determine whether any property rights are now vested in the sample donors and in family members of donors who are deceased.³⁶ It has been argued that Indigenous blood and tissue samples are inalienable from individual donors.³⁷ The samples' scientific and ethical value lies, at least in part, in their continued connection with the donor, their family and community. This connection can enable additional health and genealogical information to accrue to the sample over time. Arbour and Cook proposed a model whereby samples are considered as being 'on loan' or 'licensed' to researchers.³⁸ This approach accords with the doctrine that donors hold property rights in their samples that are held on bailment by the institutions – endorsed by *Yearworth vs North Bristol NHS Trust*.³⁹

Indigenous jurisprudence might well reject the suggestion that institutions and researchers have any rights in this material removed from the bodies of First Peoples,⁴⁰ especially in circumstances where records of consent are opaque. It may be useful to draw upon the literature on the repatriation of human skeletal remains, and reconceptualize institutional holdings of blood and hair samples in accordance with an Indigenous perspective. In the early

2000s a dispute arose in relation to the requested repatriation of the remains of 17 Tasmanian Aborigines from a London museum. The Working Group on Human Remains in Museum Collections, constituted to examine the legal status of human remains in museums and galleries in the UK, cites a relevant submission by the Tasmanian Aboriginal Centre:

[t]he argument of legitimate acquisition...is just hiding behind a technicality...It may have been donated to you or purchased by you on your side...but on our side it was plundered, stolen and taken by deceit from powerless people preyed on at their most vulnerable time.⁴¹

The complex and rather unsatisfactory outcome of an analysis constructed in property law is tempered by the careful ethics-based approach that Australian institutions have typically adopted in practice in recent years. This is encouraged by concern not to repeat past hurtful and "extractive" research practices;⁴² as well as to prioritise First Peoples' governance and decision making, while recognizing that systemic and institutional bias still exists to limit First Peoples' ability to exercise these rights. We turn now to the legal and regulatory framework for prospective management of samples, especially in terms of their research use.

Future access to and use of legacy sample collections

In Australia, future access to and use of historical blood and hair samples can fall within the scope of Commonwealth and state legislation. The *Aboriginal and Torres Strait Islander Heritage Protection Act 1984* (Cth) and state-based heritage laws are relevant, and make provision for the registration, protection and repatriation of samples in some circumstances. The state-based statutes on human tissue apply to the prospective removal of tissue (grounded in consent) but are largely silent on its subsequent storage, access, transfer and future use. Instead the use of these samples is subject to a complex overlapping system of international legal norms, national guidelines and the structures and policies of individual institutions.

International

Globally, the *United Nations Declaration on the Rights of Indigenous Peoples* (2007)⁴³ establishes international legal norms in several relevant areas, including the right of Indigenous peoples to the repatriation of human remains (article 12), and the right to participate in decision making in matters affecting their rights (article 18). The closest nexus between the *Declaration* and historical blood and tissue collections is found in article 31(1),

asserting Indigenous peoples' right to "maintain, control, protect and develop their ...human and genetic resources".

Institutions holding historical DNA samples should also be guided by the *Best Practices: Recommendations for Repositories* document issued by the International Society for Biological and Environmental Repositories (ISBER),⁴⁴ which attempts to harmonise fragmented international laws and policies. Among its key recommendations are: the need for informed consent for uses of samples unless a waiver has been applied; the involvement of representatives of affected "ethnic and social groups or communities" in not only consent processes but also research design and the dissemination of findings (L2.4.2) and an approach that respects the views and traditions of specimen donors (L2.6).

National

In Australia, two guides produced by the National Health and Medical Research Council (NHMRC) inform approaches to the collections of interest. These are, respectively, *Ethical Conduct in Research with Aboriginal and Torres Strait Islander Peoples and Communities: Guidelines for Researchers and Stakeholders* (2018); and the *National Statement on Ethical Conduct in Research Involving Humans* (2007, updated July 2018; hereafter '*National Statement*'). The *National Statement* is binding on research that is funded by the NHMRC or the Australian Research Council (ARC); two of the main funding sources for the types of research likely to be conducted on First Peoples' legacy DNA samples. So is the *Australian Code for the Responsible Conduct of Research* released by the NHMRC together with the ARC and Universities Australia in 2018; this document has further binding application across Australian research institutions. AIATSIS has also issued *Guidelines for Ethical Research in Australian Indigenous Studies* (2012) and a paper summarising principles for health research involving Indigenous Australians was published in the *MJA* in the same year.⁴⁵

The NHMRC *Ethical Conduct in Research* Guidelines outline a values-based regime focusing on spirit and integrity, cultural continuity, equity, reciprocity, respect, and responsibility, and cross-references the *National Statement*. The *National Statement* highlights the role of consent in research, pointing to a need to renegotiate or confirm consent periodically "especially where projects are complex or long-running, or participants are vulnerable" (paragraph 2.2.8). It also deals with the possibility of needing to engage with groups rather than solely with individuals, at paragraph 2.2.13:

Within some communities, decisions about participation in research may involve not only individuals but also properly interested parties such as formally constituted bodies, institutions, families or community elders. Researchers need to engage with all properly interested parties in planning the research.

Community consultation and respectful engagement with First Peoples' social and cultural practices in the design of research are also emphasized at paragraph 4.7.2.

The *National Statement* provides an avenue for researchers to proceed in the absence of consent, where a Human Research Ethics Committee (HREC) determines that a waiver of the consent requirements is appropriate (paragraphs 2.3.9 to 2.3.12). HRECs must consider certain elements in making this assessment, including: whether it is impracticable to obtain consent (paragraph 2.3.10(c)); whether there is a known or likely reason to think that consent would have been withheld if the person had been asked (paragraph 2.3.10(d)); and whether the benefits of the research "justify any risks of harm associated with not seeking consent" (paragraph 2.3.10(b)). Concerning historical collections of First Peoples' biomaterials in Australia, a waiver of consent is unlikely, due to apprehension about the harms likely to arise in that situation. Internationally, the multiple examples of Indigenous communities demanding the return of blood samples on cultural grounds should make HRECs aware of the need to proceed carefully;⁴⁶ however this is not specifically included in the *National Statement* guidance.

Institutional

Finally, individual repositories should also have governance structures and instruments to determine appropriate processes for access to and use of samples. For example, the NCIG is governed by its own instrument under the authority of the Australian National University's parent Act.⁴⁷ The preamble to this instrument sets out the University's commitment to ensuring engagement with sample donors and donor communities about use of the collection for research, as well as to the need for informed consent.

If the above governance and best practice frameworks merely point toward the need for consent with individuals and communities for the future use of historical DNA collections

from First Peoples of Australia, ethical imperatives and research findings about community perceptions mandate it. Researchers including Beaton and Hudson, McWhirter, and van Holst Pellekaan, Kowal and Garrison have written about this extensively.⁴⁸ Kowal has described the 'orphaned' genetic samples that are held in institutional freezers "unable to be mobilized without a degree of emotional and bureaucratic labour".⁴⁹ It is possible that effective mechanisms to communicate and educate, to support decision making and to enable free, prior and informed consent to be clearly signaled and withdrawn, may enable future research on these historical samples to take place. Such mechanisms should also, it is hoped, more appropriately support future sample collection and use.

First Peoples' perspectives

The perspectives of sample donors, their families and communities about historical bioscientific collections and participation in contemporary research that involves biological sampling are grounded in cultural values. By engaging with cultural perspectives there is potential to explore questions about the application of guidelines such as: what are Australia's First Peoples' cultural ethics and protocols in this context? How are they defined in relation to family and community values? How are these values acknowledged as part of research processes that include consultation; negotiation of individual and collective consent (involvement); and benefit sharing? For these individuals and communities, the research discourse on human genetics is predominately located within the context of government acts of cultural breakdown and displacement, subjugation, dehumanisation, classification and appropriation.

Understanding and acknowledging these values ultimately shape researcher interactions and partnerships with First Peoples individuals, families and communities. As Anderson and colleagues argue, "Sustained ethical relationships require the development of a mutual understanding (between researcher and researched) concerning the ethical foundations for research in Aboriginal and Torres Strait Islander contexts."⁵⁰ Cultural values are a continuum of intergenerational practices. They are embedded in the social practices of culture that move (through story, dance, language and the social dynamics of family) beliefs and knowledge between generations and into the future. Cultural identities are created from, and shaped by, values that are defined by a sense of self that is drawn from kinship, cultural and family politics and pathways of self-determination and sovereignty.

Efforts to share knowledge about genetics with sample donors and decision makers, and to improve their understanding of this field, will be instrumental to testing a project examining the feasibility of a model such as DC. It is clear that understanding the proposed research is a necessary element of providing informed consent. As outlined in *Genetic Research in Aboriginal and Torres Strait Islander Communities*: "Depending on the pre-existing knowledge of genetics and DNA within the community, informed consent may require the use of culturally appropriate tools for promoting genetic literacy."⁵¹ DC provides the opportunity to draw upon a range of different media to provide information about complex issues.

This paper has thus far outlined the cultural, legal and ethical contexts relevant to these collections of biomaterials and highlighted why it is crucial that the decisional autonomy of First Peoples donors, descendants and communities be upheld in relation to these collections. It turns now to consideration of the consent mechanisms. This analysis aims to provide a foundation for collection holders, in partnership with communities, to implement good practices for the informed exercise and withdrawal of consent to future research use of historical samples.

Broad consent and Dynamic Consent

Each legacy collection of First Peoples' blood and tissue samples forms a de facto biobank: a 'biorepository that accepts, processes, stores and distributes biospecimens and associated data for use in research and clinical care'.⁵² To facilitate the efficient use of biobank samples in future research projects that cannot be foreseen at the point of sample donation, an approach to consent known as 'broad' or 'open' consent has commonly been adopted.⁵³ Broad consent for biobanking has typically been justified on the basis that the research presents minimal risk to individual participants and is in the wider public interest.⁵⁴ It has been endorsed by the World Medical Association (WMA) Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks,⁵⁵ the Organisation for Economic Co-Operation and Development (OECD) Guidelines on Human Biobanks and Genetic Research Databases,⁵⁶ and the General Data Protection Regulation in the European Union (Recital 33). Yet the approach is not without criticism. Broad consent challenges the philosophy behind informed consent – that people should know what will happen, including the associated risks

and benefits, before they decide to participate. Critics have noted that the opportunity to withdraw, a central aspect of research participation, cannot be meaningful if participants are not aware that their samples or data are being used in a specific research project.⁵⁷⁵

Broad consent is not the only consent approach available to biomedical research; other formats exist, such as opt-in (which presumes non-involvement until participants actively sign up), opt-out (which presumes involvement unless participants actively withdraw), or tiered decision making (which subdivides consent into different categories, or tiers, and allows a slightly more nuanced decision-making approach).⁵⁸ These different approaches effectively form a spectrum spanning different levels of engagement from participants, with the research team determining the level that they consider appropriate for the research being undertaken. The extremes are presumed consent (ie no engagement, with emphasis on public interest, and the logistical challenges of reconsent) and explicit consent (ie high engagement with specific decisions).

In the context of historical collections of First Peoples' biomaterials, there are further arguments against the use of broad consent. These concerns relate to cultural sensitivity and the desire to make redress for past research practices which probably skirted the question of consent or avoided it altogether. There is also the possibility that collaborative research networks accessing First Peoples' biomaterial might include researchers who, in some cases, have minimal or no understanding of the cultural origins and value of the material being shared or analysed. Given these factors, it could be disrespectful to claim that broad consent would be in the public interest, or that any research would pose little risk of harm to affected communities. More flexible and durable consent and communication mechanisms are needed to restore such collections for future research use in a manner that promotes considerate ongoing engagement with the surviving donors, family members and communities responsible for decision making about the samples. DC may offer a solution.

DC is an approach to informed consent supported by an electronic interface that allows sample donors to revisit and review consent decisions over time.⁵⁹ It has been developed to address shortcomings in broad consent procedures for the future use of samples or data (such as in biobanking). DC establishes a lasting interaction between researcher and donor such that donors (or their representatives) can be updated about the use of the samples and data, and the progress of research.⁶⁰ This provides greater oversight for the donor or their

representative and assures the researcher that appropriate consent has been provided, particularly if the research protocol is amended over time. DC allows consent to evolve beyond a single moment, to underpin a relational approach to research. The emphasis on communication and engagement, on information delivered through a variety of media, over time, recognises the importance of catering for various informational needs and ensuring accessibility.

The opportunity provided by DC, and the reason for its consideration in this instance, is that rather than simply providing an alternative consent approach, it gives power to the participant (or in this case, group) to decide the appropriate level of engagement for themselves. This engagement is essential for building relationships of trust for communities whose values and traditions have not been respected in the past. The electronic tool can be set up to support the spectrum of consent approaches, allowing participants to decide if they wish to be involved in all levels of decision making or if they prefer to choose a broader consent.

Examples of Dynamic Consent

DC has been implemented in several research projects, for example the RUDY study in the United Kingdom, which uses DC as part of its commitment to patient-driven research in rare diseases,⁶¹ and the PEER (Platform for Engaging Everyone Responsibly) registry system developed by Genetic Alliance, in the USA.⁶² Both projects allow participants to tailor their decisions about their involvement in the initiatives, and to change these preferences at any time. Other projects that have adopted DC have reported on the value that alternative media has brought, including in the initial stages of recruitment.⁶³ These two strands of DC, the granular consent options, and the communication and engagement, are critical to the behavioral change DC intends to invoke, positioning participants at the centre of decision making and as partners in research.⁶⁴

The potential application of Dynamic Consent for use by First Peoples

First Peoples of Australia, New Zealand and the United States are themselves progressing Indigenous data sovereignty and governance through the development of shared principles and protocols. There is a fundamental recognition that Indigenous data governance requires Indigenous participation and cultural expertise across all sectors and jurisdictions as endorsed

by the Maiam nayri Wingara Indigenous Data Sovereignty Collective.⁶⁵ This marks a critical shift for First Peoples from passive research subjects or ‘specimens’ to active participants and now leaders of the discourse surrounding Indigenous data sovereignty. Mechanisms that privilege Indigenous perspectives in the DC process will be essential if it is to succeed in this context.

Partnership is the underlying philosophy behind DC, with the tool helping to develop an ongoing conversation between the research team and donors/representatives. This could be highly relevant when navigating discussions surrounding the use of historic samples and enabling and supporting First Peoples donors, family members and communities to respond to some of the questions raised by the existence of these samples.

A recent paper by Minari et al⁶⁶ initiated consideration of DC to support family decision making, in recognition of the relevance of genomics for individuals beyond the patient. This paper raised the possibility that information and communication technology could be usefully employed to manage group discussions and interaction, which could be highly applicable in this instance, where there may not be one obvious person most appropriate to lead discussions about historic samples.

DC may have specific relevance for Indigenous people if it can support group decision making. This is in line with the Maiam nayri Wingara Indigenous Data Sovereignty Collective, which asserts that Indigenous people have the right to exercise control of the data ecosystem including creation, development, stewardship, analysis, dissemination and infrastructure. This demands:

- data that is contextual and disaggregated (available and accessible at individual, community and First Nations levels);
- data that is relevant and empowers sustainable self-determination and effective self-governance;
- data structures that are accountable to Indigenous peoples and First Nations; and
- data that is protective and respects individual and collective interests

A digital consent tool could track decisions made across the group, record changes to decisions or interactions with the tool, and provide a clear and transparent record of

discussions, which would allow control to be exercised in the manner described above. DC should never fully replace face-to-face interactions, which will be vital in initiating discussion and building relationships in the first instance. Instead, DC could support interactions over time and provide additional resource in between face-to-face meetings. Allowing a DC interface to support shared decision making in the Indigenous context would require careful consideration, amongst the community, of who should have access, and who is able to make changes and edit preferences. Adopting a DC approach does not, of itself, overcome the existing challenges of identifying who (either individually or collectively) has authority to make decisions over historical samples. This must be organized very sensitively in collaboration with the community to avoid exacerbating existing suspicions relating to biomedical researchers and institutions that have collected the samples. Developing technology that could be organized and run by the communities themselves may be an option to mediate this process, however exactly how such a tool should be implemented would need careful consideration and planning. Actions to address digital literacy and collaborative efforts to develop tools that are designed to be culturally inclusive will also be important.

An electronic interface can allow for information to be transmitted through a range of media, and could be used to overcome language differences, for example using videos and animations to describe research processes. It is hoped that this will make the information more accessible to a wider audience, as compared with traditional participant information sheets. Through this media it would be possible for community members to explain to others in the group their thoughts relating to the use of samples and potential future uses, providing an electronic record of these views, and allowing other people within the community to access videos at any time and be reminded of the discussions that have been held. Keeping these records alongside the specific consent decisions allows both pieces of information to be considered in tandem, providing a wider context to the consent decisions. It also provides a record of how discussions might progress over time, such that later generations would be able to see for themselves what had been previously discussed and decided, without relying on reporting from people outside the community.

It is important to remember that in both health care and research, digital technologies have the potential to widen the gulf between those at risk of health disparities compared to the general population.⁶⁷ DC does not in itself overcome the systemic barriers that First Peoples face when trying to access digital tools.

Can Dynamic Consent meet the legal and regulatory requirements for access and use?

As indicated earlier, in the absence of clarity around the circumstances of collection and of a definitive legal structure governing the ownership, access to and use of historical First Peoples' biomaterials, a consent approach is warranted that has been developed in partnership with First Peoples. Comprehensive engagement with communities and specifically with the sample donors or, if deceased, their living relatives, about management of the samples, is imperative. A robust foundation for the research use of the samples depends upon free and fully informed consent by individuals and potentially also by groups such as community Elders and knowledge holders. It is important to note that the work to operationalize a DC approach to support family or group decision making is yet to be done. Setting up ongoing two-way communication and providing the option for people to amend their choices and to withdraw consent over time if they wish, would be part of the engagement process utilising DC. Adopting the DC approach in such a context can meet the principles promulgated by bodies such as the UN, ISBER, the NHMRC, and AIATSIS as well as the governance frameworks of host institutions, to which we referred earlier. More importantly, as long as choices signaled through a DC tool are enacted at the collection level accurately and promptly, the tool can restore power to those who are responsible for making decisions about the samples.

Practical possibilities and challenges for DC in this context

A potential disadvantage of DC in certain contexts is its reliance on electronic infrastructure, such as hardware and reliable Internet connectivity. In remote communities this could be prohibitively difficult to support in the short term and may prevent some communities having opportunity to access such tools. Whether there is opportunity to support delivery of DC through other means will be specific to individual communities and would need to be shaped by the challenges raised in each location. In some cases, central facilities may be available even if people do not have internet access in their homes. Increasing access to smartphone technology in remote communities may be more realistic than desktop solutions.

Technological barriers might be further reason to pursue a communication and consent mechanism that allows for community-wide engagement, and for discussions and decisions to

occur at a community level. For example, the process described as ‘Dynamic Consent’ could, in particular instances, refer to meetings and events specifically organised to discuss the views and concerns of the community and the reporting of these discussions could then be recorded remotely to provide a lasting record of the decision-making process and how it changed over time. This would need to be supported by equivalent paper records and resource to regularly check in with communities, to promote the underlying philosophies of DC, particularly those of partnership and ongoing interaction. The reason that DC is typically delivered using an electronic interface is that this is the most efficient method for interacting with individuals over time, between face-to-face meetings, and to allow them to access and review the record of their decision making, and information relating to how research is progressing. For a paper version of DC to properly reflect the intentions behind this approach, it must support ongoing interaction over potentially long periods of time. This is distinct from usual reconsent practices, which often try to recontact participants after significant time has passed, and suffer from challenges relating to loss of contact. DC emphasises the need to allow regular contact over time (keeping contact details updated), which in this instance would ensure that logistical challenges of recontact could never be cited as an excuse to presume consent in the future. Providing a paper equivalent would be resource intensive but could be managed to allow for equivalent systems of partnership and ongoing interaction over time, providing that care was taken to plan and organise how this could be managed and resourced.

It should be noted that DC may introduce the risk that face-to-face meetings are replaced with electronic interactions over time. The ease and efficiency of the electronic tools versus the resource required for in-person community visits would make this option tempting. However, DC has not been developed for this purpose, and is instead meant to support continued interaction between face-to-face visits, to augment an already established relationship. A further challenge is the resource requirement at the outset to develop and implement an electronic system, particularly if it is to be designed to support a range of languages and dialects. Developing content, including different types of media, will take considerable time, and may require iterative rollout of the tool. DC's capacity to allow audio and video media to be used could provide significant opportunity to support information in languages that are predominantly oral, and thus improve access to information beyond traditional approaches to paper consent, provided there is appropriate resource to develop such content. In some

instances this may be mitigated by drawing upon existing electronic resources, linking to other websites to direct users to trusted content.

In developing a DC approach, it will be important to consider the expectations for participant engagement with the tool and how success will be evaluated. For example, it may be that providing access to information is the key, and thus even if participants do not access it, the fact that they can is enough. However, in this instance it will be important to consider how to keep track of such access, in case changes in circumstance, eg a participant changing phone, limits this. In this example, ensuring DC is supported as a website rather than an app may circumvent problems associated with participants not downloading the tool, with email notifications used to remind users of the existence of the tool, especially if they need to interact with it. As DC is intended to be integrated with, rather than replace, community engagement, face-to-face interactions which provide reminders of the need to keep contact information up to date, and to alert users to any changes on the tool, may help with this ongoing interaction, especially if users decide to disable alerts and notifications.

When considering the values and benefits of a DC approach, the specific contexts in which consent is required will dictate how the tool is developed and implemented to mitigate these risks, and determine the most appropriate use of resource. This consideration must involve researchers and community representatives co-developing DC solutions that are genuinely supportive.

Conclusion

Biological materials collected from First Peoples of Australia in past decades hold promise for future genomics research. They also, in their very existence, bear traces of historic prejudice, injustice and colonisation. Research and collecting institutions that hold such legacy collections of First Peoples' biological samples are required to proceed carefully, in recognition of their legal and ethical obligations, and best practice in consultation with donors, descendants and communities. This paper provides a detailed analysis of the law, ethics and policy frameworks that apply to these collections, reaffirming the centrality of free, prior, informed and culturally appropriate consent by donors or their representatives in decisions affecting the remaining samples. It posits the usefulness of a DC approach, tailored to the specific needs of First Peoples and operationalized in consultation with them, both to meet legal and ethical requirements, and to support the exercise of their decisional autonomy.

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