Draft Aboriginal and Torres Strait Islander Genomics Health Guiding Principles and Summary

Submission by Australian Genomics, 27th October 2021

4. Do the Guiding Principles cover the main health genomic issues for Aboriginal and Torres Strait Islander people?

The Guiding Principles are centred on Aboriginal and Torres Strait Islander health and the path forward to ensure continued relationship building, strengthening genomics. This is an opportunity to build on representation of Indigenous people and support strategy development, policy, education and workforce composition. They have been developed with Indigenous genomic leaders who have ensured that Indigenous peoples rights are prioritised within genomic health care. This is significant for genomics that Indigenous people are developing frameworks and ensuring that it is informed with Indigenous knowledge. The principles promote partnerships, Indigenous self-determination, ownership and respect as the drivers for progressing Indigenous genomics. Important considerations such as Indigenous peoples knowledge systems and views are embedded within the Guiding Principles. The focus on safeguarding of knowledge, improved cultural safety, workforce capacity building and the importance of data sovereignty, informed consent and health equity have been applied with a lens that protects Indigenous rights and interests.

The Guiding Principles document offers clear expectations through the Principles. The main themes emerging from the document include the building of trust at a pace determined by Aboriginal and Torres Strait Islander people, the need for leadership roles for Aboriginal and Torres Strait Islander researchers and clinicians/health professionals in genomics, and mandatory co-design of genomic research. It offers context and rationale for these expectations using the existing literature, some examples, and Australian and international polices to support their inclusion and importance.

One thing that this document shows is the number of policies already in this space, and so its place in the policy landscape, and how it differentiates from other recommendations, needs to be clearly demonstrated. We think this document is unique in that it provides principles specific to the conduct of genomic research and clinical genomics, outlining unique and relevant issues. Therefore, the document could also lay out the specific benefits of genomics to Aboriginal and Torres Strait Islander peoples and the challenges that will need to be overcome to realise the full potential of health genomics. For example, it could be noted in the section on health disparity that the lack of appropriate genomic reference data for variant calling and the need to increase the volume and accuracy of variant data must be achieved for Aboriginal and Torres Strait Islander people to share in the rapidly accumulating benefits of clinical genomics.

Another area that could be strengthened is that of genomic literacy and the need for endeavours to improve genomics literacy in a culturally appropriate and meaningful way. Ensuring Aboriginal and

Torres Strait Islander people have appropriate genomics literacy will be essential for many of the principles to be fulfilled.

5. Do the Guiding Principles recognise the cultural diversity across Australia and can it stand as a national document?

The Guiding Principles recognise the diversity among Nations and how different knowledge systems, beliefs and culture can be incorporated into practices. Adapting genomics through the lens of many diverse communities is important to ensure the history and identities of people and their cultural practices are included. This will ensure genomics is safely implemented and engagement and participation are embraced. Indigenous systems can vary, and it is important that the diversity of communities is not considered a burden. Incorporation and acknowledgment of diverse cultures across all phases of genomic interactions and practices is critical.

Section 2.2 describes the diversity in cultures of Aboriginal and Torres Strait Islander people, with reference to the 250 languages and 800 dialects spoken. Aside from diversity in language, it would be good to provide a case study or example here, to give non-Indigenous people an understanding of how this might influence aspects such as research engagement activities, delivery of genomics as part of a health care service, or the development of genomic information materials.

To stand as a national document broad consultation with multiple Indigenous communities/Aboriginal Community Controlled Health Services around Australia is required. Was there co-design and consultation with diverse communities during development of the Guiding Principles? This also speaks to part of our response to question 10 suggesting the inclusion of a summary and/or diagram of the process by which the Guiding Principles were developed.

It is not certain whether this document reflects the different needs of these diverse cultures, or additionally, what implications geographical remoteness of communities or the challenges of federated models of healthcare might bring. There will certainly be challenges to adoption and in implementation of the Guiding Principles due to these factors.

Section 2.2 also describes the concept of wellbeing as more than just physical wellbeing which is inspiring and is starting to become recognised in broader health strategy contexts. For example, the draft National Preventative Health Strategy consulted on by the Australian Government earlier in 2021 draws upon this concept repeatedly and is the foundation of many of the proposed actions. This is an example where non-Indigenous people can learn from and adopt thinking related to culture of our First Nations people. The use of the concept of ‘health and wellbeing’, rather than just ‘health’, could be reflected further throughout document.

6. Do you have any concerns about the language used in the Guiding Principles?

Principle 4 (Data Sovereignty) is an excellent example of clear articulation of the principle and expectations in relation to it and could be referred to as an example when reformatting the other principles. The language used in some of the Guiding Principles includes definitive statements that could create issues with the implementation of the Principles. Specific examples include:

Principle 3 (b): Health Equity – "so that health benefits are returned to participants and passed on to Aboriginal and Torres Strait Islander peoples and communities". Humans can participate in projects that have limited or no benefit for the participant or community, particularly in basic human research. However, those studies may be the necessary stepping stones toward research that benefits individuals or community. Some projects have participant benefits but don't benefit the community and vice versa. The wording of this Principle indicates that there must always be benefits passed on to participants and the community. Perhaps the authors will consider adjusting the wording and to allow for a broader expectation. We suggest emphasising that co-design is used for participants and community to articulate their preference, needs and expectations for benefit and communication of study outcomes, even when there are ambiguous or no results (e.g. where genomic data is used as control or reference).

Principle 2: Cultural Safety – "To ensure the rights of future generations are not undermined by decisions made now…" "…consider all applications of genomics" and Principle 5: Informed Consent – "…and self-determination rights of future generations." These statements could have favourable and un-favourable consequences in relation to genomics and health equity for Aboriginal and Torres Strait Islander people and communities. It is not the position of Australian Genomics to dismiss or dissuade the inclusion of intergenerational concepts in these Guiding Principles, but we want to raise potential issues that these concepts could cause in the application of genomic research. We feel the *Guiding Principles* would benefit from addressing or acknowledging the limitations of researchers' current knowledge and how this could affect research involvement and health equity. This observation comes from an experience of one of the contributors to this response through the consultation process for the *Genomics Partnerships document.* In those discussions, an Aboriginal Elder raised a scenario about future data management processes and technology. The bioinformatician present could not answer the question as it required theorising on the availability of future technology and social implications for Aboriginal and Torres Strait Islander people. The Elder's response was not to do research until that question could be answered or greater understanding of technology and social implications were available. While participants and communities are well within their rights to say no research, there needs to be an understanding that researchers do not know all the potential issues with genomics that might arise in the future and affect future generations. In setting out Guiding Principles to stipulate that future generations be considered in "all application of genomics", there is the potential for future and current generations to not fully benefit from genomic research and its clinical application due to our current technical or knowledge limitations that cannot be resolved at this time. This is a sensitive trade-off that needs to be acknowledged.

Concepts of ‘co-design’ are central to this document; however, the term ‘co-design’ is not clearly defined. Also, noting that the term co-design only refers to project design and excludes co-production, co-management and co-evaluation. Terminology should be more explicit and include terms such as ‘involvement’, ‘power sharing’ and ‘being involved in decision making’, for example, ‘being involved in data access decisions’. A lack of clear definition of co-design and other terms such as ‘partnership’ significantly challenges the ability of those working in this area to adopt standardised methods and be held accountable to working within best practice.

Also of note is the origins of the phrase “nothing about us without us” which is used throughout the Guiding Principles. This is a term with central European political roots, brought to prominence in the 1990s through disability advocacy, and has since been adopted by other interest groups.

Finally, the document uses the term ‘ethnic groups’ but does not define the term ethnic. Inclusion of a definition is advised (whether it is being used in a cultural context or referring to ancestry). It would also be worth defining the terms genetics and genomics in the main document, and that genomics is used as an overarching term throughout the document. Given we have highlighted several terms for definition, perhaps a glossary could be considered.

7. Are there any improvements that could be made to the Guiding Principles?

We have some suggestions for improvements to the Guiding Principles. For example, the document could be strengthened by sharing stories of culture, customs, spirituality, beliefs, and language to help a naïve audience come to understand Aboriginal and Torres Strait Islander people and culture, as well as their views toward concepts discussed in the Guiding Principles and genomic research / clinical genomics more generally. The NCIG case study is an excellent example and one where, through its communication, non-Indigenous researchers throughout Australia working in the field of genomics understand the importance of repatriation of biological samples. What other culturally important practices can be communicated and understood? It’s possible that providing more windows into culture would leave the reader inspired to learn more, become more involved, and develop greater ambition to carry out the actions of the Guiding Principles. An example of a document where this has been done is the Te Mata Ira Guidelines for Genomic Research with Maori (2016).

From another perspective, genomics engagement and Indigenous communities is at an early stage and there will need to be further strategy on how this will be achieved and sustained. The issue of translating the importance and benefits of genomics across diverse groups who may have had minimal interactions with genomics will be a significant challenge.

Principle 6: Genomics Health Workforce - would benefit by acknowledging that there are multiple pathways to engender two-way learning between Indigenous science/knowledge holders and mainstream researchers and organisations. Building Indigenous genomics capacity can happen at many levels have a beneficial impact for both Aboriginal communities and mainstream research organisations.

Principle 2: Cultural safety - seems to have a focus on the cultural safety of future generations whereas it should also include the need for culturally safe practices by all researchers and organisations that are engaging with Aboriginal individuals and communities. There is a responsibility for these organisations to implement and evaluate a “cultural maturity” framework so that there is continual cultural awareness and cultural safety programs offered to staff (both mandatory and voluntary) and an organisational imperative to evaluate the cultural safety of its employees.

The guiding principles should offer that involvement of Aboriginal and Torres Strait Islander people should be reported in a standardised way in the public domain. For example, an open access system such as Standardised Data on Initiatives (STARDIT) could be recommended for such reporting. STARDIT was co-created with Aboriginal people, patients and experts from multiple disciplines. It can also be used to report who was involved, how, the values and purposes of genomic research. It has been adopted by the Australian Genomics working group Involve Australia for reporting: https://doi.org/10.21203/rs.3.rs-934285/v1. Similarly, co-creating ethics processes, standardised HREC pathways, and regularly checking they are fit for purpose should be built into the guiding principles.

Other brief observations and suggestions:

- An outline of the process by which the Guiding Principles were developed, including the timing of co-design and consultation processes, would be a good addition.
- “Aboriginal and Torres Strait Islander peoples have expressed their concerns relating to health genomics” is referenced (57) but seems to be mis-attributed as the reference does not describe those concerns.
- Page 13, text box 2.3 – there are two different definitions for “Culturally safe and responsive”.
- The significant mention of other policies /guidelines/ frameworks could be supported by a short description of the part(s) of those policies being referred to or are most significant to the Guiding Principles, or a box or appendix could give a summary of each document.
- Principle 3: Health Equity - in the summary document (but not the full document), there is a fourth point: (d) To ensure all Aboriginal and Torres Strait Islander peoples and communities can benefit from genomics services and research regardless of where they live.

- Suggestion to further develop aspects of genomics related to preventive health and delivery through primary health (thus aligning with other Australian Government roadmaps being developed concurrently).
- Principle 5: Informed Consent - emphasis on the need to develop resources in parallel to consent forms. For example, the need for resources in different Aboriginal and Torres Strait Islander languages.

8. Do you see any issues with being able to implement the Guiding Principles?

This document presents expectations, rationale, and background/context for the six principles. Recognising that this is not intended as an implementation document, it presents few suggestions on practical ways to enable the Guiding Principles at a research group, organisational, or health service level. Whilst organisations will vary on how this is articulated within their structure, we believe there will be a high expectation for guidance on implementation approaches. Non-Indigenous people need to hear the Aboriginal and Torres Strait Islander perspectives on implementation do's, and don'ts. Otherwise, guesswork will perpetuate the current issues seen when there is a lack of collaboration and co-design.

The issues with implementing the Guiding Principles will be reaching grass roots community and service providers and being able to translate the importance of genomics. Relationship building and engagement to ensure participation will be a long-term process that needs a sustainable strategy in place. This will be the foundation that will progress genomics. Indigenous communities priorities and achieving equitable benefits will depend on engagement. Acknowledging the competing priorities and vast amount of research that occurs within communities and how genomics will fit into this is also another challenge.

One foreseeable implementation issue is the “mandatory co-design in all genomics research studies, so that health benefits are returned to participants and passed on to Aboriginal and Torres Strait Islander peoples and communities.”

Firstly, we may highlight a potential wording issue; we anticipate the authors did not mean "all genomics research studies", but rather a sub-set of studies related to Aboriginal and Torres Strait Islander peoples in health and medical research (but could extend to basic human research, ancestry and society, criminology & forensics, or natural resources). The wording of Principle 3 should be adjusted, with further clarification provided on the scope of genomics research. Alternate options include 1) all human genomic research studies, 2) human genomics research studies that involve participants that could have Aboriginal and Torres Strait Islander ancestry (even if there is no record of ancestry or identity in the study data), 3) genomic research studies that involve participants that have identified themselves as Aboriginal and Torres Strait Islander but may include studies without any specific focus or exploration of ancestry or identity, or 4) genomics research studies were the research question pertains to Aboriginal and Torres Strait Islander peoples and communities. It is the view of Australian Genomics that until implementation guidance, workforce capacity, and engagement infrastructure is in place, that mandatory co-design should be limited to studies with targeted recruitment of Aboriginal and Torres Strait Islander people, but not studies that may recruit Indigenous people incidentally.

Wording issues aside, mandatory co-design also raises implementation issues related to the current structures and funding of research grants in Australia. Given the AIATSIS code scope is broad, it does not give specific insights into how to practically implement mandated co-design for every genomic research project. A significant risk is that mandating co-design for all human genomic studies that involve Aboriginal and Torres Strait Islander people will lead to active exclusion of these groups from research as it may disincentivise researchers, which would be an undesirable outcome of this policy. Further, while consumer engagement is essential and very highly valued it is not always needed for every study, and there is always a risk of consumer fatigue if they are engaged with too many research projects.

Can partnerships be facilitated, for example through regular workshops to hear perspectives about Aboriginal and Torres Strait Islander research priorities and to foster collaborative relationships? How would a national research program undertake co-design with the resources and time constraints of conventional NHMRC or MRFF grant opportunities (which are typically 3 years)? This envisions a need for a national agency / body to facilitate 'matchmaking' between communities and researchers based on community, and these issues raise follow on questions about who should be brokering these relationships and whether this could be incorporated by an organisation that already exists or whether establishing a new one is required.

Explicit funding for involving people in co-design and subsequent stages of research needs to be included. Similarly, methods of involvement should themselves be co-designed with Aboriginal and Torres Strait Islander people, to ensure they are culturally safe. This article is an example of co-design involvement planning, reported using STARDIT: https://doi.org/10.3390/mps4020042

In terms of building trust, whether a trusted group or organisation can be involved in dual roles of fostering research and reviewing investigators' proposals to facilitate research needs to be determined. Also, it is not clear how developing this trust relationship - which could take years - aligns with the academic funding cycles with which researchers have little choice but to fit into. Therefore, there are big, systemic changes that need to be enacted to enable researchers to conduct proper engagement and build the relationships for appropriate consultation in research. An expert advisory group could be established for researchers to commence engagement.

“Aboriginal and Torres Strait Islander peoples must be able to lead in the collection of all Aboriginal and Torres Strait Islander health genomics data” provides definitive wording on the leadership role to be taken in genomic data collection. This needs to be balanced, at least in the short term while leadership and workforce development are fostered in parallel, with being careful not to minimise research opportunities. Overall, we need to follow a strategic implementation plan to increase the participation of Aboriginal and Torres Strait Islander people in research studies to increase the knowledge base informing implementation into clinics. Also, more understanding of how this would fit with mixed ethnicity studies would be important for researchers to understand.

Improvement in the informed consent process is discussed as a part of the Informed Consent Guiding Principle, which puts forward potential improvements in the form of the examples of dynamic and tiered consent. New models of consent are another implementation challenge well understood by Australian Genomics. In addition to paving the way for new consent models are the additional layers of complexity of having consent materials available in the hundreds of Aboriginal and Torres Strait Islander languages, and communicating genomic specific issues including incidental findings, sample storage, safe data storage, access to future research and implications. Australian Genomics has developed and piloted a web application inspired by dynamic consent called CTRL which is freely available for all publicly funded research projects to adopt and modify, and we would be very willing to share our knowledge in this area.

And finally, if there is a time lag between release of the Guiding Principles document and an implementation plan, it is difficult to understand where this leaves researchers and health services with respect to addressing implementation in the meantime. It is important not to exacerbate barriers to participation in genomic research or access to genomic testing through health services. It should also be kept in mind that certain issues with implementing these Guiding Principles could be large and not restricted to addressing specific Aboriginal and Torres Strait Islander peoples considerations (i.e. some issues will be system-wide and will need to be solved more broadly).

9. Can you suggest as to how best to implement the Guiding Principles?

This will be a process that will need a multifaceted approach. It will require a coordinated effort that will centre on policy development, strengthened research, clinical practice and improved workforce development. Prioritising community care and consideration will be the building blocks to achieving gains in genomics and reducing the divide. Engagement and participation will depend on strengthening trust and ensuring that communities can see what the benefits of genomics, that these benefits are distributed back into community and how genomics can be conducted within communities that ensures their cultural needs are met.

We collectively have many ideas on how the Guiding Principles could be implemented and present a few in brief below:

- Increasing the capacity and/or number of ethics review committees with experience and accreditation to review projects involving Aboriginal and Torres Strait Islander people.
- A set of recommendations to government granting bodies, including that Chief Investigators/researchers do not need to have particular level of qualifications to lead on grant and project proposals; that funding should be built into grants for engagement, and more flexible approaches to grant timelines and milestones will be needed. This would also involve co-control of genomic project budgets with communities.
- Development of trust, co-design and shared leadership arrangements through research agreements such as has been done between Maori and research and commercial entities in NZ.
- Translation of consent into multiple languages with the aid of electronic consent platforms.
- Workshops for researchers about the principles to support socialisation of the principles and their implementation.
- Providing opportunities for researchers to connect with Aboriginal and Torres Strait Islander people, through workshops and other events such as community visits, which could also serve to accommodate group consent, and representation on governance committees for research and clinical services.
- A clearer path for bringing genomic research results to community and showing how it may positively impact the community (e.g., quality of life, reproductive options, preventive health).

Implementation could involve fostering interactions between genetic health services and the National Aboriginal Community Controlled Health Organisation (NACCHO). National endorsement at the highest level, such as the Health Chief Executives Forum (or a Collaboration reporting to HCEF, such as the proposed Health Technologies and Genomics Collaboration) should be sought to have the most impact. Operationalising the Guiding Principles in health services is likely going to come down to a state and territory health system level unless it is somehow built into the agreements between the Commonwealth and jurisdictional health departments. Understanding each health system's Indigenous policies/strategies as well as genomics strategies/policies/frameworks would be useful to determine whether these Guiding Principles could be linked or incorporated into one or more of those. There will also be a key role for Aboriginal and Torres Strait Islander Health Workers in education of patients, primary health care works, non-genetic specialists and genetic specialists which will require support from health departments.

Certain elements of the Guiding Principles may be selected for reporting as key performance indicators or built into mandatory policies for a health system/health service provider, e.g. targets for proportion of clinical genetic services appointments or genomic tests being provided to Indigenous peoples. These are ways that "system managers" of health systems can have a stronger influence over the actions of health services.

Adhering to Guiding Principles relevant to research could likely be supported through requirements of the funding agency (e.g. NHMRC), and such organisations must be prepared to lead the mandate on co-design. As implementation of the Guiding Principles will require systematic changes formally supported by organisations, government and granting agencies, an MOU or other formal structures should be considered.

There is, however, concern that if the Guiding Principles are released without an implementation or action plan, nor the required systemic changes in motion, it will not get traction with health services and research organisations. In the absence of a co-released implementation plan, further development of case studies that demonstrate the principles in action would help.

10. To improve readability, could the Guiding Principles be presented another way?

The Guiding Principles could also be adapted for grass roots community who have had minimal interactions with genomics. If this was to take place than it could be in the form of diagrams to accompany the Guiding Principles or made into language that is appropriate for diverse language groups. Tailoring the genomic needs of community to the Guiding Principles could also be a way to progress and ensure that is translated across different groups. Considering the needs of metro, regional and remote communities will be important if this is to become embedded into frameworks that will impact these populations. Considering that there is a genomic divide between metro, regional and remote communities this will a significant approach to ensure that these barriers are addressed.

The existing summary version is good, but the main document could be strengthened by inclusion of a brief statement on the scope and intention of the document and its positioning within the policy landscape. This document seems to be positioned for health services, researchers and policy makers, but there are indications that it is also for the community. An accompanying video could be developed that can speak to different stakeholder groups regarding the need for these Guiding Principles and the opportunities they present. As previously mentioned, diagrams and a video summary may help with communication to a variety of audiences. A summary of the Guiding Principles development process, including co-design and consultations undertaken, would provide additional context. Finally, footnoting references may improve readability of the document.