GENOMIC PARTNERSHIPS

Guidelines for genomic research with Aboriginal and Torres Strait Islander peoples of Queensland

QIMR Berghofer
Medical Research Institute

Genomic Partnerships: Guidelines for genomic research with Aboriginal and Torres Strait Islander peoples of Queensland

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Contents

Acknowledgement

We acknowledge the traditional custodians of Australia, the Aboriginal and Torres Strait Islander peoples and pay respect to Elders past, present and future.

We acknowledge the people, organisations and communities who have contributed to the development of this document, *Genomic Partnerships: Guidelines for genomic research with Aboriginal and Torres Strait Islander peoples of Queensland.*

Terminology

In this report the term Indigenous Australians is used interchangeably with the term Aboriginal and Torres Strait Islander peoples; we acknowledge these terms are used for both traditional custodians of Australia – Aboriginal peoples and Torres Strait Islander peoples. No disrespect is intended and we acknowledge the rich cultural diversity of the groups of peoples that are the traditional custodians of the land with which they identify and with whom they share a connection and ancestry.

The writing style and terminology in this document is based on the *Australian Government Style Manual For authors, editors and printers*, sixth edition.

Artwork description

The artworks used on the front cover, back cover and throughout the document are from pieces that explore health issues of importance to Aboriginal and Torres Strait Islander peoples.

My journey, my health

The artist, Wendy Rix, is a descendant of the Yulwaalaraay people. She is a contemporary visual artist.

Measuring Man

The artist, Robert Tommy Pau, is based in Erub (Darnley Island). He grew up in Tomwoy Town on Thursday Island and in Cairns. He is a print maker and storyteller.

Foreword

Since the discovery of DNA as the blueprint for our genetic code more than 60 years ago, the pace of change in health and medicine has been nothing short of breathtaking. Starting with studies of well-described – but relatively rare – heritable diseases, researchers quickly developed an astonishing array of new techniques to discover more and more about the causes of disease. With the advent of high-throughput technologies and super-computing, it is now possible for laboratories to process millions of genetic sequences from tens of thousands of patients.

Of course, with these advancing technologies come new challenges in how to handle the information so derived. We now have a much greater awareness of the complexities of genetic data, especially as it relates to notions of family and ancestry. In parallel, we recognise the responsibility this places on researchers and custodians to safeguard the privacy and wishes of patients.

It is critical that the benefits of the genetic revolution are shared with all Australians. To this end, genetic research must be conducted in partnership with Aboriginal people and those from the Torres Strait.

The guidelines in this document were developed with the aim of equipping researchers with the necessary understanding prior to planning their research with Queensland communities. These guidelines represent the culmination of a comprehensive consultation exercise across the length and breadth of this state, and owe their existence to the very many people who have devoted large amounts of time, knowledge and effort to bring them forth. To all of the contributors I am extremely grateful. I look forward to seeing these guidelines being used to deliver new research that will deliver benefits to all in our community.

Professor David Whiteman

Deputy Director,
QIMR Berghofer Medical Research Institute

I commend QIMR Berghofer Medical Research Institute for their commitment to ensuring that Aboriginal and Torres Strait Islander peoples are included in the discussion and debate about genomics. While these guidelines are aimed at researchers, the extensive consultation process has resulted in raising awareness at the grass-roots level giving people insight into how Aboriginal and Torres Strait Islander peoples can be involved in ensuring ethical processes in this field of research.

We are well aware of the atrocities of the not so distant past in relation to Aboriginal and Torres Strait Islander research – especially genomic research – which has resulted in suspicion and a tendency to reject research in this field. While being mindful of these issues, genomic research has many benefits for Aboriginal and Torres Strait Islander peoples with new discoveries providing the potential to make significant improvements in health and wellbeing.

This is a new era in research, one in which Aboriginal and Torres Strait Islander peoples can take an active role in shaping the future in partnership with researchers and research institutions. But in order to do so people must have access to relevant information in a way that is meaningful to them so that they not only provide input into policies and guidelines, but which also allows them to make informed decisions about the ways in which they engage in genomic research.

The world of precision medicine and technology is moving so fast that it is often difficult for the legal and ethical aspects to keep up with the complexities of this field of work. This is why we must take the initiative in being well informed about genomic research, protect those who may be less informed, and continue to challenge research which is not in the best interests of Aboriginal and Torres Strait Islander peoples. These guidelines will make a considerable contribution to ensuring that this happens.

Professor Yvonne Cadet-James

Research Coordinator,
Apunipima Cape York Health Council

Executive summary

Genomics in clinical practice is poised to be the next healthcare revolution with significant investment in research and clinical implementation occurring across Australia: it has the potential to shape Australia's health future.

To date, there has been limited involvement of Aboriginal and Torres Strait Islander peoples in genomic research due to their experience of past transgressions in conducting research. If opportunities for cultural inclusivity in genomic research do not increase, the prospect of equitable access to the healthcare benefits of clinical genomics will be limited.

To ensure genomics benefits all Australians, we have focused on developing recommendations for best-practice genomic research when engaging and partnering with Aboriginal and Torres Strait Islander Queenslanders. Our recommendations are outlined in this document, *Genomic Partnerships: Guidelines for genomic research with Aboriginal and Torres Strait Islander peoples of Queensland*.

Development of *Genomic Partnerships* involved extensive stakeholder engagement to develop recommendations and identify best practice when working with Aboriginal and Torres Strait Islander peoples on genomics research projects. Areas addressed in this document include:

- engaging with communities
- partnering to develop a research proposal
- ethical and social constraints
- collecting and storing samples
- data and reporting results

The National Health and Medical Research Council (NHMRC) has published several documents outlining the expectations for ethical research when projects involve Aboriginal and Torres Strait Islander peoples. *Genomic Partnerships* has used the NHMRC framework for best practice in research with Aboriginal and Torres Strait Islander peoples, and then expanded further in the specific context of genomic research (Figure 1). Practical advice for genomics researchers is provided along with case studies, key references, and how to approach sensitive issues identified in the consultation process.

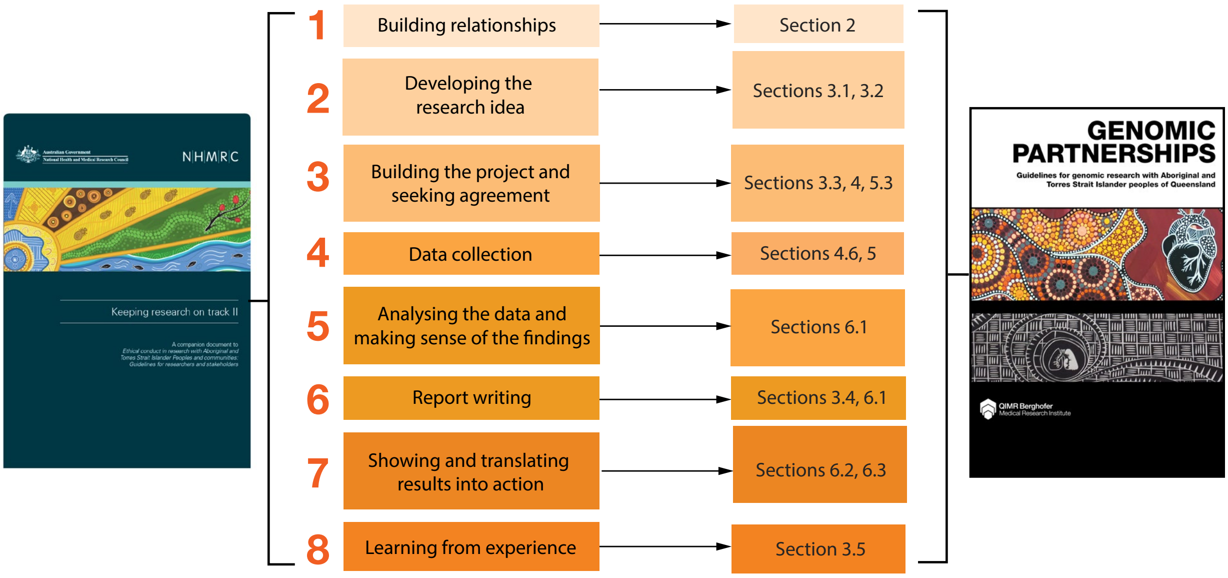


Figure 1: Overview of how *Genomics Partnerships* links to the eight steps outlined in *Keeping Research on Track II* [1].

Abbreviations

Acronym	Definition
ABS	Australian Bureau of Statistics
AIATSIS	Australian Institute of Aboriginal and torres Strait Islander Studies
AICCHO	Aboriginal and Islander Community Controlled Health Organisation
CRA	Collaborative research agreements
DAC	Data access committee
DNA	Deoxyribonucleic acid
DTA	Data transfer agreement
EGA	European Genome-phenome Archive
HGDP	Human Genome Diversity Project
HHS	Hospital and health services
HREA	Human research ethics application
HREC	Human research ethics committee
IP	Intellectual property
MOU	Memorandum of understanding
MTA	Material transfer agreement
NACCHO	National Aboriginal Community Controlled Health Organisation
National Statement	*National Statement on Ethical Conduct in Human Research* 2007 (updated 2018)
NTA	*Native Title Act* 1993
NCIG	National Centre for Indigenous Genomics
NHMRC	National Health and Medical Research Council
PHN	Primary Health Networks
PICF	Participant informed consent form
PSC	Project steering committee
QAIHC	Queensland Aboriginal and Islander Health Council
RAICCHO	Regional Aboriginal and Islander Community Controlled Health Organisation
Road Map 3	*Road Map 3: A strategic framework for improving Aboriginal and Torres Strait Islander health through research* (2018)
SSA	Site-specific application
The Guidelines	*Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* (2018)
WES	Whole-exome sequencing
WGS	Whole-genome sequencing

1 Introduction

1.1 Rationale for *Genomic Partnerships*

Substantial investment, both nationally and in Queensland, means genomics is rapidly moving from a research activity with niche clinical applications to a technology that will become part of every-day healthcare. Genomic databases and research have a significant bias to people of European ancestry [2,3]. In contrast, Arab, African, Latin American and global Indigenous populations are underrepresented in international genomics databases [3].

The lack of reference data and fundamental research for some populations has direct implications for healthcare. For clinical genomic services to provide meaningful analyses there need to be reference genomic databases and research to truly represent the Queensland population, and to provide reliable information about the frequency of genomic variants in the population and how they relate to diseases.

For many Queenslanders, this data has been made available through domestic and international genomic research and public-health initiatives. However, for Aboriginal and Torres Strait Islander peoples there is a lack of data, which in turn will result in future disadvantage and inequity in accessing clinical genomics services and the resulting health benefits.

Aboriginal and Torres Strait Islander peoples' past experiences across scientific endeavour, including genomics, has frequently been damaging. This experience in addition to the complex ethical and social implications of genomics has resulted in a limited number of genomics research projects exploring topics important to Aboriginal and Torres Strait Islander peoples.

Consultation indicated a major reason why researchers are reluctant to engage in genomics research projects involving Aboriginal and Torres Strait Islander peoples comes from a lack of experience or understanding about how to:

- start the process of developing a project
- work with communities
- navigate administrative requirements.

The purpose of developing this document was to support researchers to work with Aboriginal and Torres Strait Islander peoples to develop proposals for genomics projects.

1.2 Aim and scope

In developing, *Genomic Partnerships* we aim to provide researchers with discipline-specific, practical advice on how to engage and partner with Aboriginal and Torres Strait Islander peoples for potential genomic-research projects. Our consultation-based methodology involved: researchers, clinicians, health providers, health-policy personnel, and community representatives (see Appendix 1). The context of *Genomic Partnerships* is specific to genomics and Queensland, but some of the processes in this document may also be applicable to other areas of Aboriginal and Torres Strait Islander research or other Australian states or territories.

Each genomic project will be different, therefore for practical reasons specific advice cannot be given for every scenario. We aim to provide a starting point for best-practice strategies in genomic research involving Aboriginal and Torres Strait Islander peoples of Queensland. Ultimately, the nature of the research and the consultation process used will inform the fine detail for each individual project.

1.3 Existing national guides for ethical research

Ethical principles for research involving human participants are directed by international standards. In Australia these standards are translated as a practical framework through guidelines from the National Health and Medical Research Council (NHMRC). Researchers draw on NHMRC's frameworks and guidelines to develop and conduct ethical research. Human research ethics committees (HREC) use these documents as the basis for assessing applications for ethics approval.

To ensure that the ethics of research projects involving Aboriginal an Torres Strait Islander peoples reflect the values of the community, the NHMRC and others organisations have developed specific documents based on consultation. These publications include:

- *National Statement on Ethical Conduct in Human Research* (2007) - updated 2018 [4]
- *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* [5]
- *Keeping research on track II: A companion document to Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* [1]
- *Road Map 3: A strategic framework for improving Aboriginal and Torres Strait Islander health through research* [6]
- *Guidelines for Ethical Research in Australian Indigenous Studies* [7] - published by Australian Institute of Aboriginal and Torres Strait Islander Studies (AIATSIS).

Genomic Partnerships is written to complement and expand on the concepts outlined in the documents listed in the genomics context.

1.4 Genomic research in the context of Aboriginal and Torres Strait Islander peoples

Historically, Aboriginal and Torres Strait Islander peoples have tended to be the subjects of scientific research rather than equal partners and leaders empowered to influence and direct the research; this has extended across all scientific fields including genomic research.

The Human Genome Diversity Project (HGDP) comprised a consortium of international researchers who collected samples from Indigenous people across the globe in an effort to investigate global migration and create a database of First Nation People's biological samples for health-research purposes [8]. The design and development of the HGDP has been criticised internationally as lacking adequate consultation with global Indigenous communities [9]. As a result of the lack of consultation, Indigenous communities from several countries, including Australia, opted out of the HGDP and rejected participation occurring in their respective countries.

In Australia, the HGDP experience has had ramifications for genomic research involving Aboriginal and Torres Strait Islander peoples. The decision not to participate in HGDP was seen as an indication that genomic research was not acceptable to Aboriginal and Torres Strait Islander peoples [10]. Reports indicate the widespread criticism of HGDP led to several genomics projects being cancelled and in one case, ethics approval being withdrawn [11,12]. The stalling of genomic research involving Aboriginal and Torres Strait Islander peoples occurred in the early to mid-2000s. At the time the full extent of genomics and its relevance to healthcare was not yet realised.

In the past decade, there have been efforts to engage Aboriginal and Torres Strait Islander peoples in discussions about participation in genomic research (see Appendix 2, Part A). Currently, there are only a few Aboriginal genomic datasets (whole-genome sequencing [WGS] or whole-exome sequencing [WES]) with about 500 participants in total [13-16]. There are also several genotyping and genome-wide association studies (GWAS) [17-19]. The majority of participants in these studies are from southern and central Western Australia, and the Northern Territory. Of the WGS and WES datasets, the majority are ancestral research projects rather than health studies.

1.5 Diversity and its relevance to genomics

Indigenous Australians are largely referred to as belonging to two overarching groups: Aboriginal peoples and Torres Strait Islander peoples. While a widely-used categorisation, it is also acknowledged that this grouping under-represents the rich cultural diversity of Indigenous Australians. For more sources of information about the cultural diversity of Aboriginal and Torres Strait Islander peoples (see Appendix 2, Part B).

Estimates indicate there were more than 500 distinct clan groups in Australia prior to European settlement [20]. In a genomic context, it has been estimated the ancestors of the Aboriginal people of south-west and north-east Australia diverged around 31,000 years ago, which is similar to the divergence of the European and Asian populations [21]. This emphasises the need to consider not only the cultural diversity of participants, but also the potential relevance of genetic diversity and how this may influence analysis in genomics research.

1.6 Diversity of genome-research projects

Human-genomics research can include research into human health, ancestry or evolution. Genomics research that explores health issues can be at the level of the individual, family, discrete community or the wider population (Table 1). Beyond healthcare, genomic research involving Aboriginal and Torres Strait Islander peoples has the potential to explore ancestry and a person's connection to Country. This can be an important application of genomics for people who have experienced the transgenerational consequences of forced removal from their Country or repatriating remains kept in museum collections [14,16].

Table 1: Genomic-research study types and their applications.

Study	Definition	Applications
Cancer (tumour/ normal)	Paired testing of a tumour and a normal tissue from a single individual. The differences observed within an individual may be compared against a cohort of other participants.	Precision medicine in cancer care
Rare genetic diseases (family-based linkage)	Comparison of DNA variants within families where the relationship of participants is known. This may include sequencing affected individuals or trio-sequencing of parents and an offspring with a phenotype of interest or sequencing other family members. Family comparisons of gene variants and phenotype can be applied to help diagnose families with similar conditions, or explore more complex conditions. Annotation of the prevalence of a variant in the appropriate population is required to determine whether the variant is associated with disease.	Diagnosis and patient care
Genome-wide association studies (GWAS)	Large case-control or cohort studies that compare common genetic variations against a common phenotype or other variable. This type of analysis can also include non-genetic, environmental variables.	Common complex diseases Ancestry

2 Engaging with communities

Research involving Aboriginal and Torres Strait Islander peoples is most successful when partnerships are formed, and the research seeks to build knowledge that is significant to their community. If the community's only role is as research participants, there is a risk of repeating the past wrongs Aboriginal and Torres Strait Islander peoples have experienced.

2.1 Six core values

NHMRC's *The Guidelines* [5] outlines six core values reflecting the essential elements of Aboriginal and Torres Strait Islander peoples' culture and identity, which should be evident when consulting and collaborating in a genomics research project. These values form the foundation for a genomic research project that is respectful of Aboriginal and Torres Strait Islander peoples as both participants and partners in research (Figure 2). A detailed explanation of these values and their practical application can be found in *The Guidelines* [5], *Keeping Research on Track II* [1] and *Researching Indigenous Health: A Practical Guide for Researchers* [22]. Some communities may have additional values that need to be considered. A brief explanation of each core value quoted from *Keeping Research on Track II* [1] is in Box 1.

Figure 2: The six core values (image adapted from *Keeping Research on Track II* [1]). Source: National Health and Medical Research Council.

Box 1: Definitions of the core values quoted from *Keeping Research on Track II* [1]

Spirit and integrity

“This is the most important value that joins all Aboriginal and Torres Strait Islander Peoples’ values together. The first part, spirit, is about the ongoing connection and continuity between Aboriginal and Torres Strait Islander Peoples’ past, current and future generations. The second part, integrity, is about the respectful and honourable behaviours that hold Aboriginal and Torres Strait Islander values and cultures together.”

Cultural continuity

“Research can harm Aboriginal and Torres Strait Islander Peoples’ and communities’ knowledge, cultures, languages and identity. This value is about research being conducted in a way that protects the rights of Aboriginal and Torres Strait Islander Peoples to uphold, enjoy and protect their knowledge, cultures, languages and identity, in terms of individuals and as communities.”

Equity

“Aboriginal and Torres Strait Islander people and communities have experienced inequities as a result of discrimination and marginalisation. Aboriginal and Torres Strait Islander Peoples recognise the equal value of all individuals. One of the ways that this is shown is in commitment to fairness and justice. Equity affirms and recognises Aboriginal and Torres Strait Islander Peoples’ right to be different.”

Reciprocity

“Aboriginal and Torres Strait Islander Peoples’ way of shared responsibility and obligation is based on diverse kinship networks. This keeps ways of living and family relationships strong. These responsibilities also extend to caring for country and all within it, and involve sharing benefits from the air, land and sea, redistribution of resources, and sharing food and housing.”

Respect

“Respect for each other’s dignity and individual ways of living is the basis of how Aboriginal and Torres Strait Islander Peoples live. Within Aboriginal and Torres Strait Islander Peoples’ cultures, respect strengthens dignity and dignity strengthens respect. A respectful relationship encourages trust and co-operation. Strong culture is built on respect and trust, and a strong culture encourages dignity and recognition and provides a caring and sharing environment. Seeking consent and negotiating an agreed outcome through a formal research agreement are important ways of demonstrating respect.”

Responsibility

“All Aboriginal and Torres Strait Islander communities recognise the same most important (core) responsibilities. These responsibilities involve caring for country and all within it, kinship bonds, caring for others, and the maintenance of cultural and spiritual awareness. The main responsibility is to do no harm to any person or any place. Sometimes these responsibilities may be shared so that others may also be held accountable.” - pg. 8.

2.2 Understanding community

For Aboriginal and Torres Strait Islander peoples participating in research is not just a choice for the individual, but can also require community approval [5]. Community means different things to different people; Aboriginal and Torres Strait Islander peoples can feel connected to community on multiple levels depending on their individual circumstances and how they relate to Country. Examples of community include:

- Extended family and/or kinship group
- Traditional Owners' group
- People associated with an organisation, service or group.

Due to forced relocation from their Traditional Lands, people who live in a discrete community do not necessarily belong to the same Traditional Group. It may be necessary to consult with multiple groups in a community to gain consent and consensus for a research project.

Aboriginal and Torres Strait Islander peoples have a strong social identity linked to culture, kinship and the associated responsibilities that come from being part of a community. Few individuals can speak on behalf of a community. Knowing who to speak with and the scope of their responsibilities is important. Responsibility for decisions made on behalf of community are often bestowed to a group identified as having expertise in a specific area, for example, health, research, housing, employment, conservation, the environment, history, lore or tradition.

2.3 Engaging with community

It takes time, resources and commitment to develop a meaningful relationship with anyone, community being no exception. Having an existing relationship with an Aboriginal and Torres Strait Islander community or organisation is a good starting position; however, this does not always exist. Identifying the representative or representatives that a community rely on to act in relation to a specific area is important when making initial enquires. Beginning a conversation is not a one-step process as it will likely rely on networking with the community and the public and private sectors. We recommend the following people and organisations as a first point of contact:

- Your organisation's Aboriginal and Torres Strait Islander program, unit or group
- Queensland Aboriginal and Islander Health Council (QAIHC)
- National Aboriginal Community Controlled Health Organisation (NACCHO)
- Clinicians and health personnel working with communities
- Aboriginal and Torres Strait Islander researchers or those who advocate for Aboriginal and Torres Strait Islander peoples, including those from other disciplines
- People from the community
- People in a community leadership role such as local advocacy groups or councils.

> ***"When you build in engagement and consultation at the beginning, then you're accountable to those people that you engaged. So thinking forward to the end — the translation component — about how you're going to engage again with those same people and the end users to communicate those results... I think that is really important to think about and to build into the timeline as well, for example when you're applying for funding."***
>
> **Dr India Bohanna, College of Healthcare Sciences, James Cook University, Cairns. Cairns workshop, August 2018.**

In preparing to meet with community representatives, advocates or organisations, researchers are advised to review the NHMRC's *Keeping Research on Track II* [1]. This document provides a suggested list of questions that may be asked of researchers when projects are being proposed to community.

2.4 Starting community engagement for research projects at Queensland Health sites

Queensland's health system extends across the public, private and community-controlled sectors (Figure 3). Genomic research projects at sites that propose to recruit Aboriginal and Torres Strait Islander peoples from multiple communities may experience difficulty identifying the most appropriate and efficient pathway to engage with relevant local communities. For projects proposing to recruit patients from hospital and health services (HHS), researchers should start consultation process with:

- Queensland Health's Aboriginal and Torres Strait Islander Health Branch
- Aboriginal and Torres Strait Islander health service at each HHS with whom they propose to work
- Patient advocacy groups at the local HHS – some HHS have Aboriginal and Torres Strait Islander advocates or specialist advocacy groups, or they have established working relationships with groups in the local community.

These organisations and groups may also be able to provide advice on pathways to engage local communities.

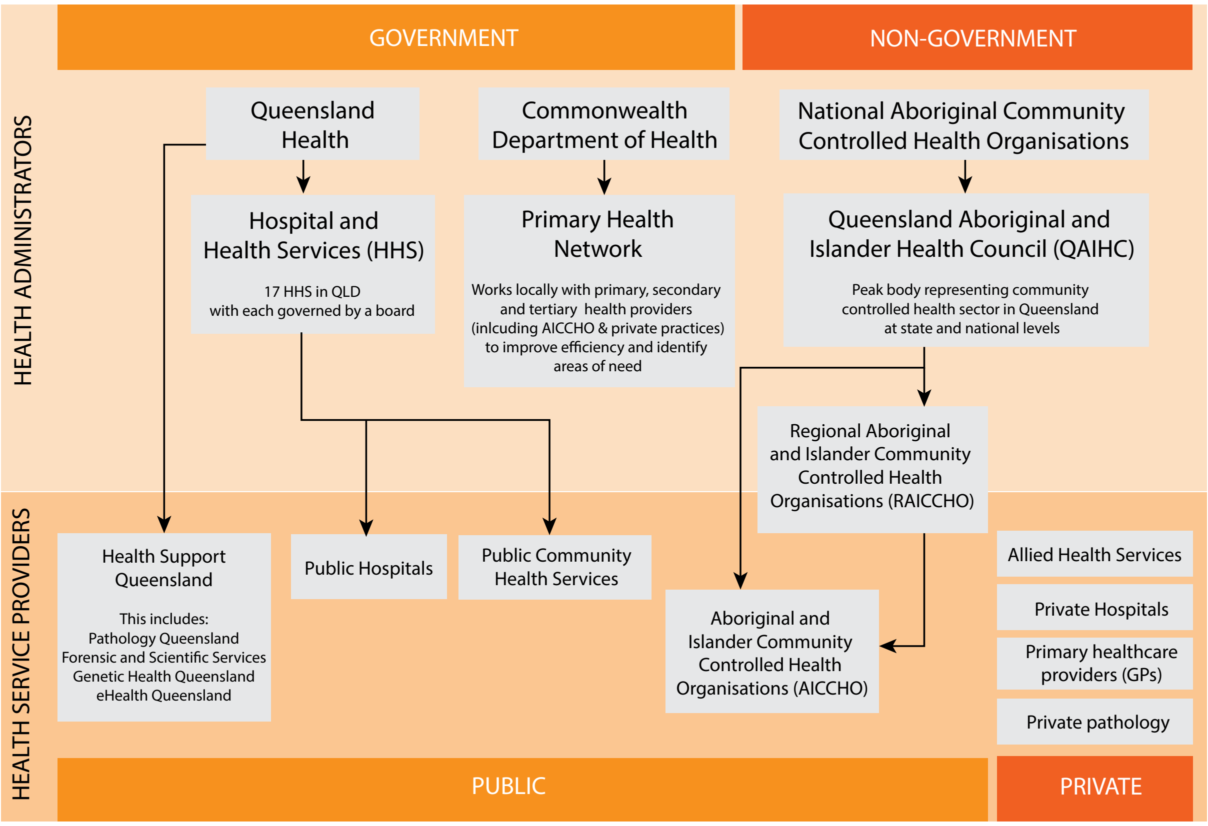


Figure 3: Summary of health-service providers in Queensland relevant to Aboriginal and Torres Strait Islander people and genomic research.

2.5 Working with community

When working with a community – be it in the city, regional, or remote locations, there are practicalities, which need to be considered. Engagement with communities and participants can be influenced by a range of circumstances and it may not be possible to predict which issues will impact a project, however; it is important to appreciate cultural, social, familial and community responsibilities can influence the ability and decisions of Aboriginal and Torres Strait Islander peoples to participate in research. Appreciating these influences and responsibilities is important when visiting, consulting and engaging with communities. Each community has its own unique set of considerations; at the stakeholder workshops participants identified the following issues:

- Individuals who live in a particular community at the time of one visit, may not exclusively reside in that community; they may have shared responsibility with other communities and may not be available on subsequent visits
- The impact of weather or emergency events, especially during the wet season
- Cultural events, festivals and celebrations and the responsibility of community to those events can impact the availability of the community
- Support services availability, for example, opening hours of health centres and the availability of health personnel, who may be casual, part time or fly-in/fly-out or drive-in/drive out
- Sorry Business and the way it is observed in the community
- The people in a particular community who grant permission for a research project can change
- Key personnel and people working in partner organisations may change roles or move on to pursue new employment opportunities.

When working with communities there may be protocols visitors, including researchers, are expected to follow. These will vary depending on the people, organisations and communities with which you are working. It is important to be flexible and build contingency into a research schedule and to respect the expectations, wishes and needs of the community.

2.6 Cultural awareness, capability and competence

When engaging in research with Aboriginal and Torres Strait Islander peoples it is recommend that the researcher aspire to conduct research, which serves to benefit and empower participants and partner with the community. Cultural competency training is a good starting point to acquire the understanding and skills necessary to build and maintain relationships with community. This training is offered through a variety of providers (see Appendix 2, Part C).

Developing cultural competence is part of continued education for researchers and as is the case with any skill it needs to be practised and refined. *Keeping Research on Track II* [1] acknowledges the benefit of mutual two-way sharing of knowledge, skills and experience for communities and researchers. In these circumstances, mentoring is important to support learning in the context of the researchers' activities. A mentor can be someone from the community with local knowledge or an experienced Aboriginal and Torres Strait Islander researcher.

It should be noted that funding bodies (such as the NHMRC) and HRECs require researchers to demonstrate capacity to effectively conduct research with Aboriginal and Torres Strait Islander peoples.

2.7 Summarising recommendations

Recommendations for developing relationships with the community

- Consider the six core values as an important basis for a relationship, but an individual community may have their own values that need to be considered
- Seek advice on who to speak with in relation to a community and the scope of their responsibilities
- Understand the cultural, social, familial and community responsibilities of Aboriginal and Torres Strait Islander peoples can influence their ability and decision to participate in research
- Develop cultural competence as an important skill and continually work on deepening your understanding through training and mentorship.

3 Partnering to develop a research project

During stakeholder workshops, a strong and recurring theme was the need to involve Aboriginal and Torres Strait Islander peoples in developing and implementing genomic research projects.

3.1 Co-designing research and incorporating Indigenous research methodologies

Co-designed research is the process where participants, who will potentially benefit from the research, are actively involved in developing the project proposal. This is considered best practice when working with all First Nations people, including Aboriginal and Torres Strait Islander peoples [23]. Employing co-design principles ensures community views, beliefs and culture are at the forefront of the research project and the community is an empowered partner in the research.

In the context of genomic research involving Aboriginal and Torres Strait Islander peoples, there are insufficient documented examples of co-designed projects. Internationally, there are a few examples of genomic research frameworks being developed [24,25]. Stakeholder consultations suggested researchers should be guided by co-design approaches used in social and health-sciences projects and by international genomic case studies.

The framework derived from working in North America First Nation communities [23] (see Figure 4), includes many of the themes that parallel our stakeholder workshop recommendations for inclusion in *Genomic Partnerships*. These include:

- dissemination - sections 3.4, 6. and 6.3
- cultural competency - section 2.6
- transparency - sections 3.3–3.5 and 5.3
- capacity building - section 3.6
- community engagement - section 2
- sovereignty and research regulation - section 3 and 4.

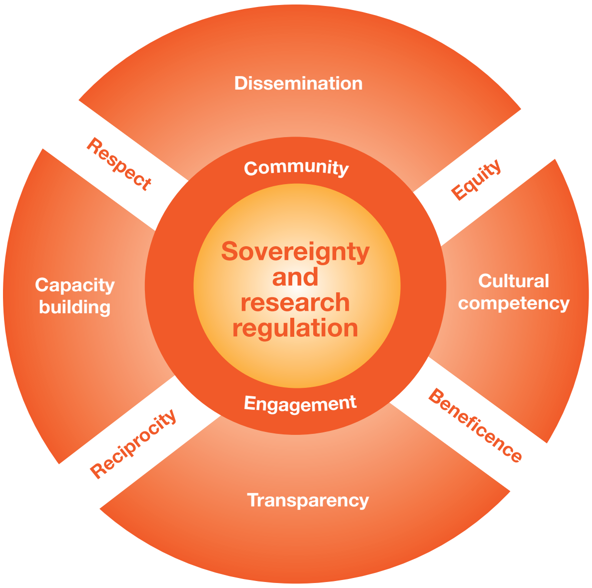


Figure 4: An ethical frame work for engaging in genomics research with Indigenous communities (image adapted from Claw, et al, 2018 [24]).

Aboriginal and Torres Strait Islander peoples have a rich knowledge and history of research. This knowledge has been communicated across the generations through storytelling, cultural practices, dance and art. The inclusion of Indigenous research methodologies can help relationship building with the community through two-way knowledge sharing and recognising the value of the community's knowledge to inform the research process.

Literature on the application of Indigenous research methodologies in Australia is predominantly for the discipline of social science, but this can still be relevant to community engagement, data collection and communication in genomic research projects (see examples in Table 2 and Appendix 2, Part D). There are examples of Indigenous research methodologies being used in the health sciences in an international context. Considering other researchers, communities and research disciplines' approaches to the inclusion of Indigenous research methodologies can highlight ways to support local applications (Appendix 2, Part D). Indigenous research methodologies vary between communities, therefore researchers will need to consult to ensure relevant application of local methods is included.

Table 2: Examples of Indigenous research methodologies that could be used in genomic research projects.

Study	Definition	Applications
Story	Teaching and learning through communication of stories that link observations to place, environment, history or process.	• Consent process (section 4.4) • Translation of results (section 6.3)
Yarning circles	An inclusive way to discuss deep issues with a community emphasising the opportunity of all participants to speak with equality.	• Project development (section 3.1-3.3) • Sample and data management (section 5.3)

3.2 Identifying and aligning priorities

It has been reported that Aboriginal and Torres Strait Islander communities often feel research does not reflect their priorities, needs and concerns [26]. Key to ensuring that research and community priorities align is to consider community needs and how these can inform research direction [1].

A recommendation from the stakeholder workshops was for researchers to start their conversations with community before establishing a project proposal. This can be achieved through informal meetings or a formal needs assessment, for example, interviews, surveys or focus groups.

In a scientific field as new and specialised as genomics, researchers may need to introduce key ideas through presentations and facilitated discussion before approaching the topic of potential research participation or partnership. Communities, organisations or stakeholders need time to understand and process information and to consider how they will be impacted if they chose to participate.

An Aboriginal and Torres Strait Islander community might choose not to participate in a research project. This can be for a variety of reasons and does not necessarily reflect negatively on the merit of a proposal or the researcher. Figure 5 shows three key elements that need to intersect to provide a favourable community environment for participation. If one community chooses not to be involved in a project it does not mean another community will not be interested in the same proposal.

Figure 5: Elements which need to intersect for the community to participate in research

3.3 Seeking agreement

Establishing research agreements with the community or representative organisations is one of the best-practice concepts outlined in *The Guidelines* [5] and *Keeping Research on Track II* [1]. While formalising research agreements is necessary for governance, it also serves to support respectful and reciprocal relationships between researchers, research partners, and the community. The types of support documents needed will depend on the project and may need to be drafted specifically for the project or adjusted from templates already available through community partner(s) or research entity based on past research projects (see Appendix 2, Part E for examples). Support documents may include:

- A letter or letters of support from the community, community partner and/or representatives of the community
- Research agreement
- Memorandum of understanding
- Study protocol
- Data plan
- Communication plan.

In circumstances where there is the possibility of commercially relevant intellectual property (IP) or financial gain from the research, this needs to be clearly communicated with the participants and the community. Discussions and agreements about compensation and ownership of IP need to be made early, even when a project is unlikely to yield these outcomes.

3.4 Communicating effectively

Two-way consultation and ongoing negotiation are key principles of Indigenous Australian studies and need to occur throughout the project [7]. Communication is critical to build trust and sustain relationships. During the stakeholder workshops it was emphasised communication plans need to outline the processes for two-way communication between participants, community and other stakeholders. Developing an agreed communication plan with the participating community as part of the project agreement is best practice and will clearly articulate expectations for researchers and the community.

Box 2 outlines processes, which should be conveyed in the communication plan and how to focus on communication methods most culturally appropriate and most like to support and sustain the relationship with the community.

Box 2: Communication plan considerations

What should be in the communication plan?

- The type of communication activities
- The goal of each communication activity
- The intended audience
- The frequency of each communication activity
- Details of how those involved can provide feedback to the research team.

What types of communication are best?

- Regular reports to governance committees
- Email updates
- Printed newsletters
- Posters or infographics on research topics
- Discussions or presentations at public forums, council and/or community meetings
- Information stalls at community events
- Newspaper or radio advertisements
- Radio, television and/or newspaper interviews
- Web-based social media promotions
- Development and update of a project website/webpage.

How to improve communication:

- Make it a discussion, not a presentation – allow people an opportunity to respond and tell their story
- Look for meaningful analogies or use narratives that are appropriate and relatable for the community
- Invite participants to tell their story of participating in the research
- Involve key local community members in hosting or presenting
- Consider carrying out several discussions with small groups rather than a large, one-off event
- Use diagrams and illustrations
- Be prepared to present without the use of PowerPoint
- Avoid jargon or technical terms (spoken or written)
- Have access to interpreters, if necessary
- Prioritise information that will engage people and community when communicating results.

3.5 Reflecting, learning and improving research processes

Learning from experience is a key theme in *Keeping Research on Track II* [1]. Across the life of a research project, it is important that researchers and the community examine, record, and evaluate positive and negative experiences. Learning from experience supports continual refining and improving the research process and can help to strengthen relationships [1].

The stakeholder workshops identified reflective activities as an important part of risk mitigation and assessment for any project; however, for genomic research reflection takes on additional importance. When researchers need to seek participants or communities re-consent for future projects, having established relationships and being committed to improved research processes is crucial to sustaining ongoing participant and community engagement. A recommendation of the stakeholder workshops was to incorporate mechanisms for reflecting and improving process into the project communication plan (section 3.4) and when convening committees (section 3.6).

3.6 Research capacity building in the community

Supporting Aboriginal and Torres Strait Islander peoples to be active participants in research ensures community values are incorporated across the project lifecycle [1,5]. Involvement in research through paid roles on the project team and committees also strengthens capacity building for Aboriginal and Torres Strait Islander communities.

Options for Aboriginal and Torres Strait Islander peoples' involvement in research projects include:

- Having Indigenous leadership for the project
- Supporting Indigenous workforce and leadership development
- Involving Indigenous researchers from other disciplines (for example, social or health sciences)
- Supporting employment of Indigenous project staff in clinical, technical, or administrative roles
- Forming project committees with Indigenous representation.

> ***"[Having someone employed within community or at a service is] building the workforce, because there are opportunities for people to come in and out of [their substantive roles]. While those people are busy doing that research component, someone can step into their role. Then you get succession planning, you get opportunities for students. That's the new generation that's bringing it forward."***
>
> **Kim Passante, Carbal Medical Service.**
> **Toowoomba workshop, August 2018.**

During the stakeholder workshops it was acknowledged there are a limited number of Indigenous researchers in the genomic and bioinformatics fields. It was suggested while workforce and leadership development in these disciplines is occurring, leadership roles could be provided by Indigenous clinicians or researcher leaders from other health disciplines.

Many research organisations have adopted workforce initiatives to support equal employment opportunities for Aboriginal and Torres Strait Islander peoples. Human resource departments and the Aboriginal and Torres Strait Islander units of research organisations will be able to give specific advice on ways to support workforce development and targeted recruitment ways.

These can include:

- Providing paid undergraduate traineeships for Indigenous students
- Providing research higher-degree placements for Indigenous students
- Providing or sourcing scholarships for Indigenous students
- Up-skilling staff at HHS or Aboriginal and Islander Community Controlled Health Organisations (AICCHO) to undertake research roles/responsibilities
- Funding research positions in HHS or AICCHO
- Identifying community representatives who can be upskilled to undertake liaison and engagement positions within the project.

At our stakeholder workshops, participants had observed that in a project team where Aboriginal and Torres Strait Islander representation is at a junior level there is the potential for a power imbalance. It was suggested an awareness of this issue and appropriate management is important. To achieve empowerment and address potential power imbalance and bias, supervisors and senior researchers are advised to undertake cultural competency training (section 2.6) and familiarise themselves with *Supporting Indigenous Researchers: A Practical Guide for Supervisors* [27].

Indigenous Australian involvement in research project committees serves to contribute to the cultural and social integrity of research. Another advantage is it enables exploration of Aboriginal and Torres Strait Islander peoples' insights across more general themes of ethics and scientific rigour. Involving community members in committees can be through membership of: project steering committees; local steering committees; and Indigenous reference groups or professional advisory groups. How to involve the community in a project will depend on its size and scope as well as the preferences of the community; it may be possible to access existing committees of community partners. For example, some AICCHO have research review committees to provide input into research involving their community (Case study 1).

Case study 1: Genetic contribution to rheumatic heart disease in Aboriginal peoples of the Northern Territory

A state-wide genomic project was established to look at genetic risk factors associated with rheumatic heart disease [17]. The project involved Aboriginal peoples from remote, rural, peri-urban and urban areas across the Northern Territory. The views and preferences of Aboriginal peoples and communities were represented in this project through multiple avenues:

- To establish the project researchers engaged with each of the 19 communities participating in the project to gain insight into the project development and consent process. This included seeking agreement from the community to allow the research to occur.
- An Aboriginal governance committee was established to have oversight of the study. Agreement was needed from this committee for any protocol or project changes which occurred.
- Aboriginal peoples had representation on the project's other committees including: project steering committee, clinical sub-committee and scientific sub-committee.
- Aboriginal researchers and clinicians were members of the team of project investigators and research staff.

3.7 Summarising recommendations

Recommendations for developing a successful research project

- Work with the community to involve them in the planning and co-design of the research project
- Consider how to align the project to the community's interests, priorities and needs
- Work with community to build understanding and trust, then develop supporting documentation outlining processes and agreements
- Document a clear communication plan supported by best-practice communication methods
- Embed reflection and continuous learning to improve processes throughout the project lifecycle
- Nurture the project by involving the community in leadership roles and actively supporting workforce development and capacity building.

4 Considering ethical and social concerns

Ethical and social considerations were the single most discussed topic at the stakeholder workshops as they are critically important to build relationships and to promote trust within the community. Social and ethical considerations also represented the area where stakeholder workshop participants held the most diverse views.

4.1 Ethical approval and research governance

Aboriginal and Torres Strait Islander peoples are a participant group in human research who require specific considerations [4]. This is reflected in the need for human-research ethics applications (HREA) to demonstrate evidence of community consultation and agreement to participate in the research prior to seeking ethical approval (section 3.3).

Some HRECs do not have the capability to assess a HREA involving Aboriginal and Torres Strait Islander participants or genomic research. There are a number of options available to HREC to assess applications outside of their expertise including:

- Engaging an external expert panel member or members to provide specialist advice
- Engaging a specialist HREC to assess the elements of the application not within the scope of the principal HREC (while the principal HREC provides assessment of the elements of the application within their scope)
- Supporting the researcher to access a different HREC, which is able to assess the application.

Workshop participants strongly recommended that research teams consult with the HREC they intend to submit to during the planning phase of the project.

There are HRECs that specialise in the review of applications for research involving Aboriginal and Torres Strait Islander peoples. At this time no specialist HREC exists in Queensland. Some specialist inter-state HREC may consider reviewing an application from outside their state (fees may apply) – see Appendix 2, Part F.

In addition to ethical approval for research, Queensland Health HHS and AICCHO require site-specific approval by research governance before research can begin (Figure 6). This needs to occur if all, or part, of the study recruitment or activities are occurring within a HHS service. The process for site-specific approval varies considerably and researchers need to consult with service partners to determine the site-specific approval process during project planning.

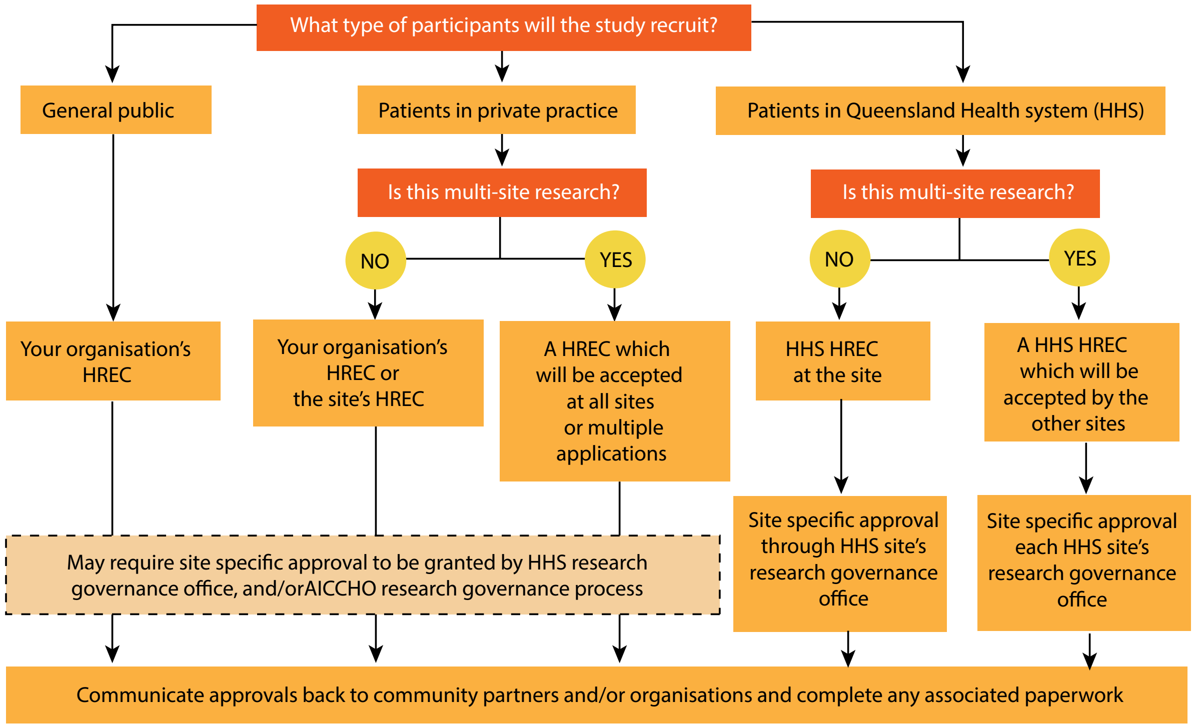


Figure 6: Flow chart of ethical approval process for research.

4.2 Obtaining consent

The importance of consent is a central element of the NMHRC documents on ethical human research [1-3]. An individual has the right to choose if they wish to participate in genomic research. However, circumstances, social protocols or personal choice may give rise to other people consenting on an individual's behalf (Figure 7). This is particularly relevant when re-consenting as a person may choose to defer consent to subsequent genomic research projects to another person or group during the primary consent process, or may no longer able to provide consent.

The types of consent used for individuals will depend on the project and the community participating. An individual may wish to consult with their family or community Elders before making a decision to participate in research – this is still individual consent. There are also some communities where social protocols prompt an individual to defer the decision of consent to family or Elders. Consequently, a research project's consent process needs to accommodate the communities needs.

When partnering with Aboriginal and Torres Strait Islander peoples in research there can also be the need for community consent [1,4]. Evidence of community consent occurs through agreements (see section 3.3). Participants in the stakeholder workshops emphasised community consent – or lack of – does not override an individual's right to choose to participate in research.

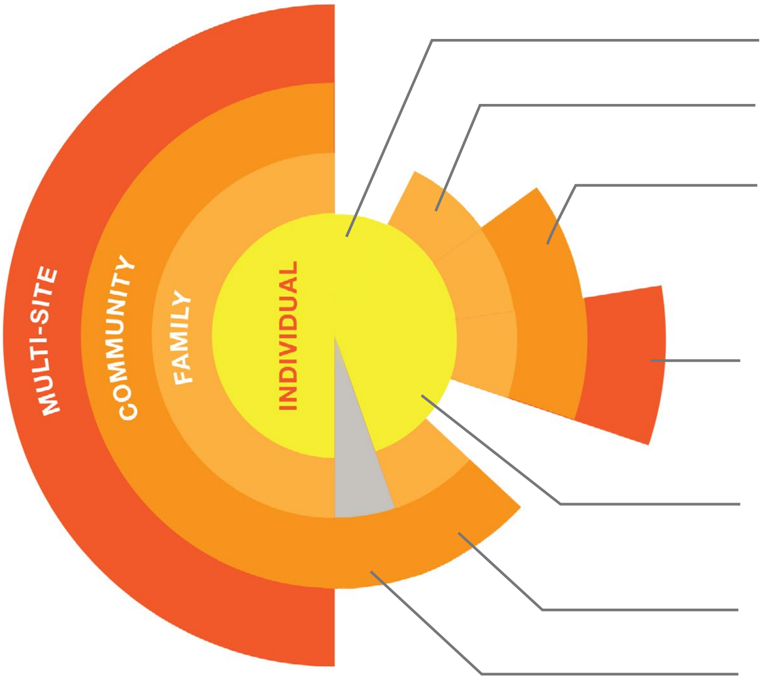
> ***"…the communities are actually authorising. They're doing the final sign off and saying this can happen. The ethics committee is part of that process… I think it's an important part, but it's not the final sign off."***
>
> **Andrew Crowden, A/Prof in Philosophy at The University of Queensland and member of AIATSIS research ethics committee. Brisbane Workshop, July 2018.**

Community consent relates to permission:

- For research to occur in a community or at a community organisation
- To report about the topics of the research results (see section 6) in the context of the community or community organisation (in alignment with any agreements made).

Opinions at the stakeholder workshops varied significantly when discussing community consent for projects where a large number of communities will be participating (for example population level studies). There was agreement that community consultation was needed, but opinions around the process in practical terms varied. It ranged from the need for every participating community being consulted and providing consent, through to a major overarching community organisation being consulted and providing endorsement for the project.

For researchers a starting point would be high-level consultation with representative organisations to discuss the proposed project. During consultations with representative organisation it may be recommended that researchers require community consultation and should move onto this as the next step. It may be that consultation leads to a single-study protocol for consent for all participants or there may need to be a different protocol for Aboriginal and Torres Strait Islander peoples or individual communities. This decision will come from the community consultation process that explores the dynamics of the individual project.



Consent

Individual consent

Individual consent with family consultation

Individual and community consent (with or without family consultation)

Multi-site study with multiple communities giving consent plus individual consent

Re-consent

Individual re-consent

Community and individual re-consent

Established data governance committee if individual consent to external governance provided

Figure 7: Level consent and re-consent that can be applied to genomic research projects with Aboriginal and Torres Strait Islander peoples.

4.3 Categories of research consent

The value of genomic data is its potential to be used to investigate a broad range of research topics secondary to the original project. The *National Statement* [4] defined three broad categories for consent – specific, extended and unspecified. Internationally, First Nations people participating in research with a consent model similar to the extended or unspecified category have objected to the types of subsequent research conducted, as shown in Case study 2.

During the workshops there was general consensus that unspecified consent for undefined future work was not a preferred option for Aboriginal and Torres Strait Islander peoples. Participants agreed this type of consent was unacceptable because it reduced autonomy for individuals and the community to make informed decisions about their involvement in research. Re-consenting was considered best practice for Aboriginal and Torres Strait Islander peoples involved in secondary research projects. The other strategy suggested is to establish data custodians with a governance structure to approve secondary use of genomic data (Case study 4).

Case study 2: Havasupai Tribe lawsuit after secondary use of DNA samples

In the late 1980s, a research partnership between Arizona State University and the Havasupai Tribe was established to look at genetic links to Type II diabetes [28]. The consent process included broad consent to other projects, but the consent process was only available in English, which was most of the participants' second language. By 2003 the Havasupai became aware that the samples had been used for additional studies including mental health, migration, and rates of consanguinities, which are taboo subjects for this tribe. A lawsuit was filed citing issues with consent, mishandling of blood samples, unapproved use of data, and breach of medical confidentiality. The lawsuit resulted in an out of court settlement and the repatriation of the samples [28].

4.4 Creating a consent process that works

Consent is an individual's autonomy to make an informed decision about joining a research study and ensuring the consent process focuses on participant care through risk management [1]. One of the central covenants of consent is that it is informed; it is difficult to provide true informed consent for genomics as our understanding of implications and future uses of data is still developing.

Participant informed consent forms (PICF) and associated participant information materials are the most widely accepted form of consent documentation for HRECs to review. It is important to recognise that research consent is more than just a signature on a piece of paper. The process of informing a participant about a research project – whether it is done verbally, in writing, or through multimedia presentation (or combinations of these) – is as much a part of the consent process as the final agreement (Case study 3). Workshop participants recommended several things to consider when developing a consent process for genomics research with Aboriginal and Torres Strait Islander peoples (Table 3).

Table 3: Potential consent elements and considerations to support best practice in consent protocols.

Consent element	Considerations
Language	Where participant information and consent documentation is written in English, researchers should aim for a Grade 8 readability level. This rule of thumb applies to all people, not only Aboriginal and Torres Strait Islander peoples. This can be checked by using readability apps freely available online and word processing software. Genomics concepts are not part of the general public's language. Using storytelling and metaphors can be helpful when explaining complex topics such as genomics.
Alternative consent strategies	For some Aboriginal and Torres Strait Islander peoples and communities, English is not their first or even a routinely used language. It may be the local language or dialect does not include a written form. In these cases, the researcher needs to develop participant information and consent documentation in the languages of the community and use a combination of non-written media including: • Spoken consent process (with permission these could be recorded) • Audio or video presentations • Diagrammatic or pictorial representations Working with a community to develop these resources is important. It aids communication of technical concepts, promotes community ownership and involvement along with sharing responsibility for the appropriateness and effectiveness of resources. It is increasingly common to have a suite of consent resources available to enable the consent process to be adapted to an individual's communication preferences (Case Study 3).
Consent personnel	The person taking the participant through the consent process needs to be familiar with the study, potential implications for the person and their family, and the consent process. The participant and the research partner may prefer this role to be met or supported by a local community member or medical service staff rather than researchers.
Reduce external influences	In health-care settings there needs to be a clear delineation between clinical care and research to ensure research participation is informed and voluntary. Creating a consent process that separates the two is important. This can be achieved by: • Having staff specifically responsible for the consent process • Separating the research consent process from clinical consultations by either: time, location or paperwork. When seeking consent, it is important to understand social norms and societal structures can cause a participant to feel pressured to consent. Researchers should be aware of the influence external factors can have on voluntary consent. In particular: • Financial reimbursement can adversely bias a participants choice to consent • Community approval being seen by individuals as consent on their behalf • The position or standing of the person involved in the consent process may influence participation • Views on authority, for example, doctors can be viewed as respected authorities who can be trusted. External factors will vary from person to person and community to community. Awareness of potential issues helps the researcher to work with the community and its representatives to develop a consent process, which respects the preferences of the community.

Case study 3: Consent process for a research project to determine the genetic role in a cancer cluster in east Arnhem Land communities

In east Arnhem Land, a project was developed in partnership with the local communities to explore potential genetic causes of a cancer cluster [18]. This project included two types of consent [29]:

- Approval from each participating community for researchers to work in the community and with local health services
- Consent from the individual, expressing willingness to participate in the project.

Prior to seeking community approval for the project the researchers first undertook engagement with each community with the support of an Indigenous reference group (IRG). The IRG assisted researchers to develop engagement and communication strategies appropriate for the individual community. The consultation process established the project was a priority and identified preferred methods for the protocol and expected benefits for the communities. The research team, which included members of the local community, then approached local health boards and clinics to develop community participation agreements based on the protocol developed during consultation.

For individual participant consent researchers worked with community representatives to develop a consent process customised for the project and region. An illustrated book presenting concepts around genetics and inheritance was developed along with a recorded explanation in a widely-used regional dialect to accompany the book. As an addition to the resources, the consent process was conducted as a discussion in the presence of an interpreter. Once the consent discussion was completed, participants who chose to participate had their consent recorded in written form. Potential participants were given the opportunity to leave and think about whether they wanted to participate, or discuss participation with their family. This time gave people a way out of participating without having to say ‘no’. This was a cultural consideration in these communities.

When considering participant risks in developing a genomic research consent process, there are standard considerations that apply to any person or participant cohort, for example: incidental findings, return of results, discrimination (genetic or insurance), and implications for family. In addition to these general considerations, there are also additional risk factors for Aboriginal and Torres Strait Islander peoples. The relevance of each risk will depend on: the topic of the genomic research, how genomic data is managed, and how the community is involved. The following are risk factors identified through the consultation process (Table 4). There may be additional risks that researchers need to consider.

Table 4: Risk factor to consider when developing consent for genomics research projects.

Risk factor	Consideration
Identification or re-identification of individuals and communities	There are circumstances where communicating the study site or the name of the community involved can contribute to identification of individual study participants due to small community size. There needs to be an agreement with community if the location or name of the community will be made publicly available. If community or study site is to be communicated publicly, individual participants need to be informed of the risk of re-identification, especially in small communities or when studying rare diseases, which may be considered to be of a sensitive nature.
Self-determination of cultural identity	Genomics has the potential to create conflict between the scientific narratives of ancestry versus the views and beliefs of an individual or community. Aboriginal and Torres Strait Islander peoples have the right to have their cultural identity, views and beliefs reflected in the public narrative created by research. Researchers conducting genomics projects that have the potential to provide an alternative narrative on local beliefs should discuss this issue with community and participants.
Self-determination of Aboriginality	Some people with Aboriginal and Torres Strait Islander ancestry do not identify as Indigenous, or do not know about their ancestral links to Country. In assessing participant risks, consideration must be made of the potential for an individual's or a community's identity to be challenged by the results.
Social stigma and taboo subjects	For Aboriginal and Torres Strait Islander people some topics could be taboo or have a social stigma associated with them. There are also topics that are considered the purview of a specific group (example being topics related to Women's Business and Men's Business). There needs to be consideration of the potential for discrimination or social stigma in the context of internal to community (local views and norms) and external to community (wider societal views and norms).
Land rights	In Australia, the *Native Title Act 1993* (NTA) recognises the traditional rights and interests of Aboriginal and Torres Strait Islander peoples. While the NTA does not require proof of ancestry through DNA testing there are concerns voiced through community consultation that genomics could be used for this purposes in the future. While it may not be a current risk it is a current concern for participants and communities, and as such should be addressed in conversations especially for projects that explore ancestry or are seeking unspecified consent.
Family	Familial risk from genomic research can be applicable to anyone. Depending on the risk associated with the project this factor may need to be considered in the context of cultural protocols observed by the study participant and their family.

The Guidelines [5] emphasise the importance of research involving Aboriginal and Torres Strait Islander peoples benefitting the community and the individual participants. It was recognised in the stakeholder workshops that not all genomic research will have direct benefit to the individual participants or communities. There still needs to be explicit discussion of benefits, or lack of, and for potential benefits not to be over emphasised. These discussions should include explanations of the benefit that a researcher gains from conducting research. Communities can then decide if the benefit to both parties is balanced. An individual's or community's perception of what constitutes benefit will vary greatly. Some people and communities will accept benefit that is derived from altruistic participation as acceptable while others may not find this acceptable.

4.5 Rights and responsibilities

Keeping Research on Track II [1] contains an in-depth exploration of the rights of Aboriginal and Torres Strait Islander peoples when participating in research. It is the researcher's responsibility to uphold and facilitate the realisation of these rights during a genomic research project. Practical guidance on how researcher's responsibilities can be demonstrated is provided in *The Guidelines* [5].

As stated in the NHMRC's *The Guidelines* (2018) [5]: "Aboriginal and Torres Strait Islander peoples have a right to assert and retain ownership of the cultural and intellectual property related to the information that is provided for research projects." While *The Guidelines* refer directly to spoken and created objects [5], there is an expectation among international Indigenous communities that this also incorporates data [30] including genomic sequences. Discussion and negotiations should be held to define ownership and co-ownership of knowledge to provide adequate recognition and shared benefit, especially when traditional knowledge (including genomic and genetic information and biological samples) are used, or may be used, for commercial purposes [1].

4.6 Historical data and samples

There is a long and often negative legacy of Aboriginal and Torres Strait Islander peoples' involvement in research [26]. Biological samples and associated data, collected prior to the introduction of modern human ethical standards of research, remain in collections. These samples can be devoid of consent or there can be questions of the legitimacy of consent. There is the potential for these historical samples to be used for genomic research; however, workshop participants emphasised there must first be engagement and consultation about the research and consenting or re-consenting of individuals or communities as shown in Case study 4. When exploring options to use historical samples for genomic research projects:

- **Unprovenanced samples** – consultation should occur with the communities from the region where the sample was collected.
- **Provenanced samples** – consultation should be with the individual or, if deceased, their family or the community.

Case study 4: The National Centre for Indigenous Genomics

The National Centre for Indigenous Genomics (NCIG) based at the Australian National University is an organisation which serves as custodian for a collection of historical samples and data from Aboriginal and Torres Strait Islander peoples collected during the 1950s to 1970s. There are acknowledged issues around the validity of consent for samples in this collection. As such, NCIG is working with communities across Australia to gain consent from individual owners or their descendants for the use of these samples in genomic research. Central to the management of NCIG collection is the Board and a Collection Access Committee both having majority Indigenous membership. This committee assesses review applications by researchers to access the NCIG collection. (For more details on re-consenting and data access process see http://ncig.anu.edu.au/)

4.7 Defining Aboriginal and Torres Strait Islander genomic research

In the NHMRC documents on ethical human research [1,4-6], there is no clear definition of when a research project transitions from being a study of the general population to one that requires specific consideration of the needs of Aboriginal and Torres Strait Islander peoples.

For NHMRC grants that fund research with Aboriginal and Torres Strait Islander peoples, the funding rules requires at least 20% of the proposed participants are Indigenous Australians for the research to be eligible for these grants [31]. This is a cut-off for funding allocations and is not a suitable recruitment benchmark to define Aboriginal and Torres Strait Islander research.

Based on the discussions at the stakeholder workshops there are three types of research involvement, which can apply to Aboriginal and Torres Strait Islander peoples:

- **Specific research:** intentionally recruits Aboriginal and Torres Strait Islander participants as all, or part of, the research cohort.
- **Non-specific research with Indigenous interests:** has a participant cohort from the general population (incidental recruitment), but where Aboriginal and Torres Strait Islander participants are either:

    (i) over-represented in the cohort being studied

    or

    (ii) results relating to Aboriginal and Torres Strait Islander peoples will be derived from the data.

- **Non-specific research:** has a participant cohort from the general population that can include incidental recruitment of Aboriginal and Torres Strait Islander peoples where no conclusions are made about Indigenous Australians or their communities.

For specific research and non-specific research with Indigenous interests it was recommended at the stakeholder workshops that researchers consult, engage and partner with relevant communities to develop the proposal and progress the project. This process of engagement is not required for non-specific research.

There are circumstances where results relating to Aboriginal or Torres Strait Islander peoples or communities from non-specific research are identified after the commencement of a study. Thereby changing the study to non-specific research with Indigenous interests. To determine if and how findings can be reported researchers should consult with communities or relevant organisations about the potential for the publication of findings from the existing study (see section 2.3). This process may lead to recommendations from the community for the development of specific research project – requiring new ethics application or amendment and re-consenting of participants.

The definition of non-specific research with Indigenous interests outlined in this document indicates that this type of research applies when results relating to Aboriginal and Torres Strait Islander peoples will be derived from the data. The opinions of stakeholder workshop participants about the research activities that are encompassed by the word “results” varied greatly. It was agreed that when presenting conclusions about Aboriginal and Torres Strait Islander peoples, there needs to be community consultation, as outlined throughout this document. However, there was disagreement on whether the following activities could occur without community consultation:

- Publishing summary data (for example the number of Aboriginal and Torres Strait Islander participants)
- Data analysis of ancestry for validation purposes
- Collection of data on indigeneity.

The reason for differences in opinion tended to relate to how potential participants perceived risk and social concerns – these will vary considerably between projects. For example, a project on mental health may have more risk to the community or individuals and has the potential to involve discussion of social taboos.

The recommendation was to consider the individual project in the context of risk to Aboriginal and Torres Strait Islander peoples and community and social concerns. If you are unsure of what the risks and social concerns are for your cohort or project topic, seek advice from organisations and groups listed in section 2.3.

4.8 Summarising recommendations

Recommendations for developing a consent process that reflects community needs

- Consult with your HREC early in the project development
- Individual and community consent may be needed for projects
- Creating a consent process with the community will assist in making sure it is fit-for-purpose
- Incidental recruitment of Aboriginal and Torres Strait Islander peoples may require community engagement – this needs to be considered on a project-by-project basis.

5 Collecting samples and storing data

During the stakeholder workshops there was emphasis that biological samples for research should be seen as gifts that need to be respected. How samples are handled and the management of associated data needs to reflect the community's expectations.

5.1 Understanding belief systems

The human body and all parts of a person – this can include excretions – can be part of Aboriginal and Torres Strait Islander peoples' belief systems [32]. They serve as a connection to the environment, family and the community (past, present and future). The way in which this connection is emphasised, perceived and respected, through ceremony and cultural practice, will differ between communities, families and their members [32]. For this reason, the specific methods of collection, type of samples collected and their storage are important topics to discuss with communities and participants when planning your research.

During the stakeholder workshops to develop *Genomics Partnerships*, the following recommendations were made:

- All researchers, scientists and project personnel should treat samples as precious and significant to the people from whom they were collected
- Where possible, samples should be stored on Country
- The person gifting the sample should be made aware of the intended use of their sample and the process of repatriation or disposal once it no longer of use.

5.2 Repatriating samples

Repatriation of samples and data is a common concern globally for Indigenous people who participate in research (Case study 5). Due to the connection between an Aboriginal and Torres Strait Islander person's physical body, spirit and Country [32], there may be circumstances where participants or communities want samples or data returned. During project development, the topic of repatriation and disposal of samples and data should be discussed. Important points to clarify include:

- Local beliefs within the community (there may be more than one view point)
- What materials the repatriation processes refer to, for example, samples or remaining DNA
- Timeframes for the return of samples or data
- Process for returning samples or data
- Process for the disposal of samples or data
- How preferences for repatriation should be recorded, for example, individual consent form or community agreement.

> ***"It's part of the air, it's part of the waterway, we dip our feet in that water, we dip our feet in the sand. And DNA, spiritual genetics, touches everything in our connection, to people, to land, air, sea, tideway, everything."***
>
> **Dr. Yvette Roe, Senior Research Fellow,**
> **Mater Medical Research Institute Ltd.**
> **Brisbane Workshop, July 2018.**

Case study 5: Māori kaitiaki (guardianship) and karakia (blessing) of biological samples

In response to the increased interest in genomics as a health care and research tool, the Māori people of Aotearoa New Zealand developed guidelines that reflected their cultural beliefs. These two guideline documents outlined expectations for genomic research and biobanking [33,34]. The application of these guidelines in research has resulted in the Māori community having an active involvement in the use of their biological samples and data.

Examples of the guidelines in practice are:

- When samples are no longer needed, Christchurch Tissue Bank provided participants with the option of specimen disposal with a Māori karakia (blessing) [35]
- To ensure culturally appropriate management of samples, the genetic research project formed a kaitiaki (guardianship) group of Māori people. The group's task was to ensure the research benefited the community. Additionally, the project employed two Elders to act as "spiritual guardians" for the samples [35].

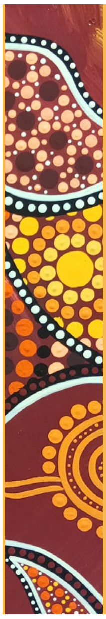
5.3 Developing research protocols with communities

Many participants in the workshops, without life-sciences backgrounds, were surprised that sequencing and human genomic data was routinely stored in databases overseas, not managed by the researchers conducting the study, or that laboratory or analysis may be performed by commercial companies who provide genomic services.

Research-study protocols need to reflect a community's expectations, customs and beliefs [1]. This is particularly important for how data and samples will be handled and managed long term. During the stakeholder workshops it was clear community expectations and understanding of research processes may not align with current genomic research practices in Australia or internationally.

To ensure agreement between researchers and the community, in-depth discussions about research protocols need to occur when developing a research agreement. Each individual community will have their own areas of interest or concern, which need to be considered in the development of a community-endorsed protocol. There also needs to be agreement about how protocol changes will be discussed, communicated, and approved. Transparent governance structures to assess research protocols and changes are beneficial for all parties in this context (see section 3.6). The stakeholder workshops identified points for consideration when developing the research protocols to act as a starting point for discussions with the community (Box 3).

Sometimes researchers may not be able to change their protocols to reflect a community's expectations; however, this does not mean the research protocol must be accepted as given. There will be times when researchers and the community reach an impasse with regard to a research protocol and as a consequence development of the project is unable to continue.



Box 3: Communication plan considerations

Where

- Will samples be stored?
- Will samples be processed?

How

- Will samples be stored and for how long?
- Will samples be disposed of when requested/required?
- Will samples be repatriated when requested/required?

Who

- Will have access to the sample?
- Will have access to the data?

What

- Commercial companies will have access to the samples or data?
- Government agencies will have access to the samples or data?
- Access to samples and data need to be considered over time?

5.4 Storing samples and data, and managing access

Funding bodies and scientific publishers increasingly require genomic data, which is de-identified to be made available to other researchers. Currently, data sharing occurs through:

- Publically accessible files, for example in journal articles, supplementary materials, study- or organisation-specific data repositories
- Public databases, which contain de-identified genome variants from many people to estimate population frequencies, for example the Genome Aggregation Database (gnomAD) or for clinical significance, for example ClinVar
- Restricted-access databases which may be governed by data-access committees (DAC)
- Shared directly between researchers as collaborative data sharing through research agreements such as materials or data transfer agreements (MTA or DTA) and collaborative research agreements (CRA).

The *National Statement* [4] states the expectation that all research participants can withdraw from a study at any time; however, once a study has been published and the data made available to other researchers it is not always possible to withdraw an individual's data. This needs to be appropriately discussed during the consent process. The inability to withdraw data from a study can be due to an individual participant's data not being identifiable within a cohort and also practical issues with retracting or preventing the continued use of a published or shared dataset.

Data sharing will vary between projects depending on the nature of the genomic dataset and community expectations. Information on data storage and management process should be included in individual consent documents and be based on agreements with the community. When discussing community preferences for data sharing, topics to explore include:

- **Data sharing and storage options –** this may include options for how the data is shared, who governs access to the data, options for not sharing specific types of data, and how to manage expectations of funders and publishers.
- **Types of data that can be shared –** For example anonymised data, de-identified data or identifiable data.
- **Withdrawal of data –** from studies in the context of preferred data type, sharing and storage.

In recent years there has been a growing international movement for Indigenous people's rights to data sovereignty and data governance [30,36]. While this is not a topic specifically captured in the current NHMRC documents it is a changing and important consideration for genomics researchers partnering with Aboriginal and Torres Strait Islander communities. Once community expectations and preferences have been confirmed, options for data access and management can be developed and may include:

- Establishing a DAC and an agreed process for the sharing of datasets from the research (for example see Case study 4 and 6).
- Working with existing data governance or access committees
- Establishing a process, and written agreements for sharing data with collaborators
- Identifying sources of research funding and publishers that will accommodate the community's expectations on data management.

Case study 6: Desert exome collection data access

In the early 2010s, an Indigenous community from the Western Desert region of Australia partnered with researchers to better understand genetic factors of body mass index and diabetes [13,15]. As part of the planning for the project the community agreed to have genomic data from the study stored in the European Genome-phenome Archive (EGA) with a DAC to provide governance around granting secondary access and use [15].

To access this de-identified dataset, qualified researchers are required to submit a summary of their research to the DAC for assessment [15]. For access to be granted the research project must be in health research to align with the original participant consent. Once approved, the research team signs a data-access agreement, which includes the requirement for results from research be returned to the DAC for dissemination to the community. This data–access process has been successfully used to look at the genetics of blood-type profiles of Aboriginal peoples in an effort to reduce complications from blood transfusions [37].

5.5 Determining sample size

Genomic researchers have demonstrated communities of Indigenous Australians who were geographically distant at the time of European settlement have vast genetic separation [14, 21]. This may have implications for genomic research investigating common and complex diseases where rare or low-frequency genetic variants are involved and have the potential to be specific to a population with a particular ancestry.

During the stakeholder workshops the following areas were identified as crucial points for consideration during project planning in relation to sample size:

- Using data or samples from other collections to increase sample size and reduce potential participant burden associated with redundant sampling
- Considering the likelihood of recruiting a sufficient number of participants to detect a variant of interest
- Considering the relevance of participant ancestry to analysis
- Considering the diversity of the study population's ancestry.

5.6 Summarising recommendations

Recommendations for developing successful collection and data storage protocols

- Understand the importance of the community's belief systems in relation to reporting and storage
- Involve the community in discussions on guidelines around sample collection and storage, drawing on best-practice examples and community concerns
- Ensure all issues relating to data collection and storage – access, repatriation, storage, withdrawal – are agreed on and a process for change and governance implemented before the project begins
- Appreciate the need to develop protocols to meet the needs of the community, as well as, the funding body and publishing entity requirements.

6 Reporting results

A clear recommendation from the stakeholder workshops was for community to be involved in planning the reporting process - both when establishing research project and before research results are reported.

6.1 Interpreting and publishing of results

Research and the reporting of research findings have the power to create positive outcomes for a community, but can also have negative consequences. The examples of the Havasupai Tribe lawsuit after secondary use of DNA samples (Case study 2) and media misrepresentation of the MAOA gene research findings (Case study 7) highlight how potentially damaging publishing without consultation can be.

When publishing or presenting research involving Aboriginal and Torres Strait Islander peoples, the stakeholder workshops recommended researchers avoid speaking on behalf of the communities. Best practice involves researchers working with community partners and their project governance committee to develop reports, which respect and empower Aboriginal and Torres Strait Islander voices [1].

Suggested examples of how self-determination and empowerment of the Aboriginal and Torres Strait Islander voice is best supported in research outputs include:

- Interpreting results in the community context when developing reports
- Using language inclusive of the community's culture, values, and beliefs
- Identifying results that can cause harm to participants or the community, for example, promoting negative stereotypes or health disparity.

To ensure the community's voice is represented in scientific reports community members need to be able to contribute directly to scientific journal articles and presentations. This can be achieved through:

- Proofing or advising on documents and presentations
- Co-authoring documents or researchers co-presenting with community members
- Interviewing community members, individually or in groups
- Meeting with community representatives, project governance or Indigenous reference groups.

For projects with non-specific or incidental recruitment, which do not have a direct link to a discrete community, an Aboriginal and Torres Strait Islander peoples' perspective can be achieved through consultation with or seeking advice from:

- Team members or leaders who are able to represent the community perspective
- Indigenous governance committees for the project (see section 3.6)
- Aboriginal and Torres Strait Islander peoples' partner organisations
- Your research organisation's Aboriginal and Torres Strait Islander peoples' unit.

Consulting and seeking advice does not constitute permission to make statements about Aboriginal and Torres Strait Islander peoples or communities. Consulting provides general advice on the language used in documents, appropriate cultural and social perspectives, and provides suggestions of other people who the researcher might approach for specific advice to assist in crafting a report document that is respectful.

Case study 7: Media misrepresentation of the MAOA gene research findings

In 2006, researchers reported at a conference and media interviews that a genetic variant in the X chromosome-linked monoamine oxidase A (MAOA) gene had a higher prevalence in Māori males than males with European ancestry [38]. The gene had previously been described as the 'Warrior Gene' due to its link with aggression, risk taking and addiction. This led to media reports that Māori males are genetically predisposed to criminality, violence and addiction. This resulted in an outcry from the Māori Community, as the research promoted negative stereotypes. There was extensive criticism of the researchers in their handling of the communication of the research results.

Since this controversy, research on Māori expectations in the ethics of genomic research [39] has culminated in the creation of *Te Mata Ira: Guidelines for Genomic Research with Māori* [33].

6.2 Reporting outcomes to community

Returning research results to the community is a separate process from publishing results in scientific journals, presenting at conferences, or returning research results to individual participants. Reporting to a community involves communicating results in a format to suit the areas of interest and level of technical understanding of the intended audience [26]. Even if the project had no results, researchers should still return to the community to discuss why this was the case. This information can help the community and its research partners to make informed decisions when approached about future projects.

When returning results to community partners the stakeholder workshops suggested:

- Translating findings into community benefits
- Avoiding jargon and technical terminology
- Disseminating findings in a way, time and manner to reflect community preferences.

For suggested strategies on reporting outcomes to a community, see section 3.4. For projects not conducted in a discrete community, for example, those in metropolitan areas or state-wide studies a more general outcomes-based dissemination strategy may be required including:

- Reporting to partner organisations
- Working with partner organisations to produce communications suitable for their members
- Developing media releases (traditional or social) with a specific focus on engaging health organisations and community media such as local radio stations or newspapers
- Writing articles for industry publications (for example, *Australian Indigenous HealthBulletin* or *The Medical Journal of Australia*)
- Reporting directly to participants through newsletters, a project website or social media.

6.3 Translating knowledge

Research results have the potential to have tangible benefits for Aboriginal and Torres Strait Islander peoples and communities. While the type of benefit derived from research varies between projects, plans and processes need to be in place to ensure knowledge translation occurs [1]. Translation of genomics research is relevant for health-related topics, but it can also be relevant to the social context, for example, the application of ancestral genomics in the repatriation of human remains held in museum collections [16].

For research knowledge to be translated to benefit people and communities there needs to be support from technical experts to:

- Engage with key stakeholders with an interest in (or responsibility for) the research area – local, state and federal government representatives, policy makers, funding bodies, key health or health-related institutions
- Seek local expertise from the community to translate research in a way that incorporates needs and experiences on end users into policy and practice, or in the development of health promotion and literacy resources.

6.4 Summarising recommendations

Recommendations for developing a successful research project

- Consider publishing, reporting to the community and translating research during the planning of the research
- Work with community partners to include the Aboriginal and Torres Strait Islander voice when reporting research findings
- Return results to the community in a way that reflects the agreed communication strategy
- Separate the processes of returning results to the community from the process of publishing results
- Require and plan for knowledge translation to support benefits to be realised from genomic research – practice, policy and public dissemination

Glossary

Anonymised: the removal of data from a dataset that can make an individual identifiable. Done in a way that the identifiable data cannot be reassociated with the dataset.

Community: as defined by *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders* (2018) (*The Guidelines*) [5] – page 25: "…is recognised as a complex notion incorporating cultural groups, geographic groups or groups sharing common interests. It may include a group or organisation and is also a term used to describe a shared view amongst Aboriginal and Torres Strait Islander Peoples."

Country: as defined by *The Guidelines* [5] – pg 26: "Aboriginal and Torres Strait Islander Peoples have spiritual, physical and cultural connections to their land. Aboriginal lore and spirituality are intertwined with the land, the people and creation and this forms their cultural identity and sovereignty. Country takes in everything within the landscape – landforms, waters, air, trees, rocks, plants, animals, foods, medicines, minerals, stories and special places. Community connections include cultural practices, knowledge, songs, stories and art, as well as all people: past, present and future."

Cultural protocol: the code of conduct that guides behaviours of a particular cultural group. This code of conduct can be in the forms of customs, lore or codes. Using cultural protocols is a way of demonstrating respect for the cultural traditions and people of the community.

De-identified: the separation of data from a dataset, which could potentially make an individual identifiable or executed in a way that the identifiable data may be reconnected with the dataset.

Extended consent: is defined and paraphrased from the *National Statement on Ethical Conduct in Human Research 2007 (National Statement)* [4] – pg 18: "...given for the use of data or tissue in future research projects that are: (i) an extension of, or closely related to, the original project, or (ii) in the same general area of research (for example, genealogical, ethnographical, epidemiological, or chronic illness research)."

Genomic research: as defined by the *National Statement* [4] – pg 101: "Research with the potential for hereditary implications which may range from single gene genetic research to whole genome sequencing and any other 'omic' research (e.g. exomic, proteomic, etc.) with potential hereditary implications. Genomic research includes the full scope of 'genetic' research."

Identifiable: a dataset containing data that can identify the individual.

Sorry Business: the traditional, customs and practices performed at the passing, illness or ill health of a person of significance to the individual, their family or their community.

Specific consent: is defined and paraphrased from the *National Statement* [4] – pg 18: "limited to the specific study under consideration."

Unspecified consent: is defined and paraphrased from the National Statement [4] – pg 18: "given for the use of data or tissue in any future research."

Women's or Men's Business: traditional, customs and practices performed by women or men only. In the modern context of health and the Community, when discussing topics considered Women's or Men's Business there is usually a splitting of genders to discuss issues.

Appendix 1

Consultation process for *Genomic Partnerships*

Genomic Partnerships was developed from stakeholder consultation. The consultation process consisted of two workshops held at five locations across Queensland (Table 15) in July/August 2018 and February/March 2019. The workshops involved participants from the research community, health services, ethics, health-policy sector, and members of Aboriginal and Torres Strait Islander communities.

During the first workshop stakeholders were asked to consider:

- Whether Aboriginal and Torres Strait Islander peoples of Queensland are interested in exploring possible genomic research partnerships?
- What is important for genomic researchers to understand and appreciate when developing research partnerships?
- Possible content for inclusion in *Genomics Partnerships*
- Issues impacting genomic research and partnership, including those specific to Queensland.

The second workshop presented a draft version of *Genomic Partnerships* for comment. After each workshop participants and those people not able to attend were provided with the opportunity to comment on the workshop discussion points through two electronic consultations.

In conjunction with the workshops, community forums were held at a local AICCHO or HHS to introduce the concept genomic research and genomic medicine to local community members through an informal discussion and a question and answer session. Perspectives voiced during the community forums were used to inform the discussions during the first workshop and the development of *Genomic Partnerships*.

Table 6: Number of participants for each *Genomic Partnerships* activity.

	1st workshop (July/Aug 2018)	Community forum (July/Aug 2018)	2nd workshop (Feb/March 2019)
Brisbane [1]	23	5	22 13
Toowoomba	8	7	7
Rockhampton	5	4	4
Townsville [2]	10	15	2
Cairns	6	4	3
Weipa	-	8	-
Thursday Island	-	8	7
Electronic consultation	9	-	21
Total participants (not incl. electronic submissions)	**52**	**51**	**58**

[1] Two workshops were held in Brisbane during February 2019.
[2] Townsville workshop cancelled due to floods. Video meeting were held as replacement.

Project Steering Committee

In addition to the consultation and engagement process outlined above, a Project Steering Committee (PSC) was convened to oversee the development of *Genomics Partnerships*. Committee membership comprised of highly-respected experts from the Aboriginal and Torres Strait Islander health-research sector and genomic-research community.

The following link provides greater detail around the governance and project methods.
https://www.qimrberghofer.edu.au/genetiqs-project

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Queensland Aboriginal and Islander
Health Council

Appendix 2

Other resources

A. Works on genomic research with Aboriginal and Torres Strait Islander peoples

Issues and acceptance of genomic research involving Aboriginal and Torres Strait Islander communities:

- Kowal, E., Rouhani, L., Anderson, I. (2011) *Genetic Research in Aboriginal and Torres Strait Islander Communities: Beginning the Conversation*, The Lowitja Institute, Melbourne. https://www.lowitja.org.au/page/services/resources/Science-and-health-conditions/genomics/Genetic-Research-Communities-Beginning-the-Conversation
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Case studies of researcher experiences with genomic research involving Aboriginal and Torres Strait Islander peoples:

- McWhirter, R.E., Mununggirritj, D., Marika, D., Dickinson, J.L., Condon, J.R. (2012) *Ethical genetic research in Indigenous communities: challenges and successful approaches*. Trends in Molecular Medicine, 18(12): 702-708. https://www.sciencedirect.com/science/article/abs/pii/S1471491412001645?via%3Dihub
- Kowal, E., Pearson, G., Rouhani, L., Peacock, C.S., Jamieson, S.E., Blackwell, J.M. (2012) *Genetic research and Aboriginal and Torres Strait Islander Australians*. Journal of Bioethical Inquiry, 9(4): 419-432. https://link.springer.com/article/10.1007%2Fs11673-012-9391-x

B. Cultural diversity

- Families and cultural diversity in Australia: Aboriginal families in Australia https://aifs.gov.au/publications/families-and-cultural-diversity-australia/3-aboriginal-families-australia
- Indigenous languages map of Queensland http://www.slq.qld.gov.au/resources/atsi/languages/Indigenous-languages-map
- Aboriginal and Torres Strait Islander histories and cultures resources https://www.qcaa.qld.edu.au/downloads/aust_curric/ac_ccp_atsi_cultures_history.pdf

C. Cultural capability resources

- Cultural capabilities training providers list in Queensland
  https://www.datsip.qld.gov.au/people-communities/cultural-capability
- Cultural capability training strategy
  https://www.datsip.qld.gov.au/resources/datsima/involved/cultural-capability-training-strategy.pdf
- RACGP Cultural Awareness and Cultural Safety Training
  https://www.racgp.org.au/the-racgp/faculties/aboriginal-and-torres-strait-islander-health/education/post-fellowship/cultural-awareness-and-cultural-safety-training

D. Indigenous research methods

- Alison Laycock, A., Walker, D., Harrison, N., Brands, J. (2011) *Researching Indigenous Health: A Practical Guide for Researchers*. The Lowitja Institute, Melbourne.
  https://www.lowitja.org.au/resources-researchers
- Wilson, S. (2011) *What is Indigenous research methodology?* Canadian Journal of Native Education, 25:2. 175-179.
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E. Research agreements

- Kowal, E., Pearson, G., Rouhani, L., Peacock, C.S., Jamieson, S. E., Blackwell, J.M. (2012) *Genetic Research and Aboriginal and Torres Strait Islander Australians*. Journal of Bioethical Inquiry, 2012. 9(4): p. 419-32. (Example Memorandum of Understanding)
  https://link.springer.com/article/10.1007%2Fs11673-012-9391-x
- Aboriginal Health and Medical Research Council of New South Wales Ethics Committee Model Consent Form - Aboriginal Community organisations
  https://www.ahmrc.org.au/publication/ahmrc-ethics-committee-model-consent-form-aboriginal-community-organisation/

F. Aboriginal and Torres Strait Islander specific HREC

- Lowitja Ethics Hub – HREC contact list
  https://www.lowitja.org.au/page/research/ethics/ethic-hub/menu/contacts
- NHMRC – Ethical Guidelines for research with Aboriginal and Torres Strait Islander Peoples
  https://www.nhmrc.gov.au/research-policy/ethics/ethical-guidelines-research-aboriginal-and-torres-strait-islander-peoples

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