

Ethics Protocol

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The [ANU Human Research Ethics Committee](#) has approved the ethical aspects of NCIG's work (**Ethics Protocol # 2015/065**). Participants who have concerns or complaints about how NCIG works are advised to contact:

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1. Plain Language Summary

NCIG is established by the [National Centre for Indigenous Genomics Statute, 2016](#), which provides the legal foundation for ANU's management of the [NCIG Collection](#). Under the Statute, which has the force of federal law, the [ANU Council](#) gives custodianship of the Collection to an [Indigenous-majority Board](#).

NCIG develops and manages a collection of Indigenous biospecimens, genomic data, and documents/records (the NCIG Collection) to be used by researchers and doctors to the benefit of the people who have donated samples to the Collection, their communities and descendants, the broader Indigenous community, and the general Australian community.

This protocol describes how NCIG complies with the [National Statement on Ethical Conduct in Human Research](#) in achieving this objective.

As detailed below, this protocol applies to research conducted internally by NCIG as an essential part of developing the NCIG Collection (referred to as **NCIG Research**). It also covers how NCIG controls access and use of material in the Collection in specific research projects (referred to as **External Research Projects**).

It does not, however, cover External Research Projects themselves, which require separate ethics protocols in order to access and use material in the Collection.

Ethical oversight of NCIG's work presents challenges that go well beyond the requirements of most research projects.

As documented in this protocol, NCIG addresses these challenges by going beyond the usual level of ethical compliance that applies to most research projects in two important ways.

1. It includes the NCIG Board in ethical oversight to ensure appropriate Indigenous involvement.

The Board's involvement also ensures a capacity to innovate, to develop new standards of ethical practice that go beyond current compliance requirements, and to improve

processes over time in light of operating experience and in response to community expectations.

2. It has incorporated the following attributes into the fabric of the organisation, which in combination ensure that high ethical standards are maintained over time in the face of change:
 - Good governance
 - Close community engagement
 - Adherence to strong principles
 - Rigorous planning and reporting
 - High levels of transparency and accountability.
 - Application of sound policies and procedures
 - Implementation of internationally recognised technical and operational standards
 - Research excellence

2. Introduction

NCIG was initially set up in 2013 to implement recommendations of a committee of eminent Indigenous Australians from outside ANU – the ANU Consultative Committee on the Indigenous Collection (CCIC).

The CCIC considered a range of options for ANU’s collection of biological samples that had been obtained from Indigenous Australians for scientific research between the 1960s and early 1990s.

It recommended that ANU develop the Indigenous Collection into a national resource.

In line with the committee’s wishes, NCIG now plays an important role in creating and managing an internationally important resource “for high quality research with substantial beneficial outcomes for the Indigenous people of Australia” and “a model for the conduct of genetic research with Indigenous populations both in Australia and elsewhere in the world”.

NCIG was formally established by the [*National Centre for Indigenous Genomics Statute, 2016*](#).

Through this statute, and in recognition of the Collection’s immense cultural, historical and scientific importance, ANU commits to ensuring:

1. that the Collection is held and added to under appropriate Indigenous custodianship.
2. that there is proper engagement with Indigenous people and communities from which the samples and records were collected about any use of the Collection for research.
3. that appropriate consents are obtained for any research using material in the Collection.

The ANU Council’s purpose in making the Statute is to establish an appropriate framework to ensure Indigenous governance of, and the application of best practice for, the conduct of any research using material in the Collection.

Under the Statute, the Council delegates the custodianship of the Collection to the NCIG Board. The Board makes policies for the management of the Collection as detailed below.

NCIG IN A NATIONAL AND GLOBAL CONTEXT

In recent years many large international genome projects, sometimes involving hundreds of thousands of participants, have focused on diseases such as diabetes, schizophrenia, Alzheimer's disease and cancer.

The substantial costs of these projects are justified by their potential to improve health care and medical practice.

Other large genome studies aim to characterise the nature of genome variation in general populations or in specific population groups in different parts of the world.

The [Catalogue of large-scale genomics initiatives](#) lists 50 such initiatives in 29 countries, including 6 that cover broad geographical regions. Appendix A of The Australian Council of Learned Academies' report on the [Future of Precision Medicine in Australia](#) provides another comprehensive list of such projects.

Prominent examples include: [The US-based 'All of Us' Research Program](#); [The Estonian Genome Project](#); Genomics England's [100,000 Genomes Project](#), [France Génomique](#); [The UK Biobank](#); [Chinese Precisions Initiative](#).

These population-based studies are funded by national governments, international agencies, private foundations, for-profit companies, and sometimes by people participating in the research.

The principle aim of these projects is to establish data resources to support research and development and clinical practice. They represent the vanguard of a general shift towards data-driven approaches to medical research and practice.

Currently, human genome research is largely focused on people of European ancestry, to whom the research benefits will also largely flow. Most current large genome studies focus mostly on people of European ancestry.

This inequity, which has arisen for historical reasons, is being addressed through large projects involving indigenous communities including [The International Genome Sample Resource](#); [H3 Africa](#), [the Carlos Slim genomics initiative in the Americas](#), [The Saudi Human Genome Project](#).

Local, national and regional projects are needed because health and disease are affected by subtle differences in the genomic makeup of different human populations. These studies provide a reference against which disease associated genomic variation can be understood in local populations and in populations of mixed ancestry.

Indigenous people have the poorest health of any group within Australian society. Despite its potential to contribute to 'Closing the Gap' between the health of Indigenous and non-Indigenous Australians, genomic research involving Indigenous Australians has been extremely limited.

Indigenous peoples have good reason to be cautious about involvement in this kind of research. Historically, oppression of Indigenous people was supported by scientific theories of genetically based racial inferiority.

At the same time, if Indigenous people are excluded from new areas of research such as genomics they may miss out on emerging developments in health care.

Far from helping to alleviate health inequalities, these developments may increase the health gap, with Indigenous Australians unable to benefit from new forms of personalised health care as these become available to non-Indigenous Australians.

WHAT NCIG PLANS TO ACHIEVE

NCIG provides a framework for appropriate and respectful Indigenous engagement in genome research in Australia. It contributes to global efforts to extend opportunities for Indigenous people to participate in genome research without risking social or cultural harm and to ensure that Indigenous people share in benefits that arise from the research.

Benefits from research supported by NCIG are long-term and may not make immediate contributions to Indigenous health priorities identified by the [Close the Gap Campaign](#) or the [Council of Australian Governments' National Partnership Agreement to Closing the Gap on Indigenous Health Outcomes](#).

The principles and practices established by NCIG serve as best-practice guidelines for funding agencies and researchers.

NCIG uses genomics and bioinformatics facilities that are components of the [National Collaborative Research Infrastructure](#). While benefiting from these facilities, NCIG also ensures that national research infrastructure is strengthened by the resources and expertise developed to support its activities.

NCIG's outreach program helps address the concerns about Indigenous participation in science education identified in the Report of the [Review of Higher Education Access and Outcomes for Aboriginal and Torres Strait Islander Peoples](#).

NCIG adds to existing academic enrichment programs that support Indigenous post-graduates, undergraduates and high school students interested in the sciences.

ETHICAL OVERSIGHT OF NCIG'S OPERATIONS

Ethical oversight of NCIG's operations presents a number of particular challenges. Some of these are shared with other large biomedical data projects. Others are specific to the purpose of the Centre.

NCIG, along with many other large data-centric projects has an indefinite life span. This has a number of consequences that present challenges to reporting and monitoring through standard HREC processes.

There is no expected end date to the project. The Centre anticipates that its role and operations may change over time in response to community wishes and expectations, new technologies, changes in legislation and the regulatory environment and the sheer pace of scientific progress.

NCIG's approach to ensuring high ethical standards recognises the need for flexibility.

An approach has been taken that adds two key elements to the standard HREC approval process.

1. A number of key features are built into the fabric of the organisation, which in combination ensure that high ethical standards are maintained over time in the face of change.
2. The NCIG Board's involvement ensures a capacity to innovate, to develop new standards of ethical practice that go beyond current compliance requirements, and to improve processes over time in light of operating experience and in response to community expectations.

ANU HREC approval is required for the protocol and for variation to the protocol.

INSTITUTIONAL FEATURES THAT ENSURE HIGH ETHICAL STANDARDS

NCIG, as an organisation, has attributes that combine to ensure the highest ethical standards in all the Centre's operations. The specific implementation of these principles are detailed in the protocol below.

Good governance

The *National Centre for Indigenous Genomics Statute 2016*, which has the force of federal law, establishes the foundation of strong Indigenous governance and a legal framework for the ethical conduct of NCIG's operations.

Close community engagement

NCIG has developed and maintains close and enduring relationships with the Indigenous communities with which it works.

Adherence to strong principles

The NCIG Board has established and oversees the implementation of a set of core principles that govern the conduct of the Centre's work.

Rigorous planning and reporting

NCIG has a 5-year strategic plan, and statutory requirements to provide an annual operational plan to the ANU Vice Chancellor and an Annual Report to the ANU Council.

High levels of transparency and accountability

NCIG uses international best standards for management and practice, including careful documentation and record keeping.

Application of sound policies and procedures

The NCIG Board has set policies for engagement with communities and management of the Collection that are implemented through well documented procedures.

Implementation of internationally recognised technical and operational standards

NCIG implements international best practice standards to all areas of operation, as detailed in its library of manuals and standard operating procedures.

Research excellence

NCIG is committed to the highest standards of research excellence, backed by sound research planning, careful record keeping, and open, transparent and reproducible research practices.

3. Governance

NCIG is established by the [National Centre for Indigenous Genomics Statute, 2016](#).

Under the Statute, NCIG has the following functions:

- To hold the Collection, and add to it, in accordance with international standards
- To engage with Indigenous communities, organisations and people in relation to the Collection, particularly those associated with material in the Collection
- To promote the use of the Collection, including by engaging with researchers and research institutions outside the University
- To support research using the Collection
- To do anything incidental or conducive to the exercise of any of its other functions.

[The NCIG Board](#) has 9 members, a majority of whom must be Indigenous Australians, and an Indigenous Chair.

A Board meeting quorum is a majority of Indigenous members present.

The primary function of the Board is to act as the custodian of the NCIG Collection.

As custodian of the Collection, the Board is responsible for its management and use, and for the appropriate addition of material, in accordance with international standards.

The Board's functions under the Statute are to:

1. Oversee the operations of the Centre
2. Approve policies for the Centre
3. Provide advice to the Council and the Vice-Chancellor about the Collection
4. Promote the Collection as a national and international resource
5. Seek funding for the purposes of the Centre, including for research and community engagement
6. Encourage the Centre to promote the use of the Collection, including by engaging with researchers and research institutions outside the University
7. Exercise any other function given to it under this instrument
8. Do anything incidental or conducive to the exercise of any of its other functions.

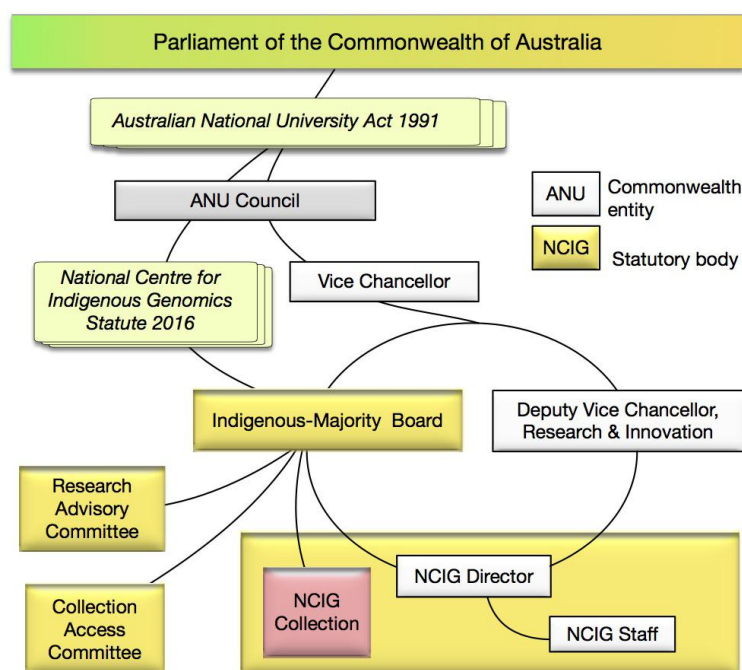


Figure 1. The NCIG governance framework.

IMPLEMENTATION OF THE STATUTE

The Board:

- holds quarterly meetings
- has a [5-year Strategic Plan](#) to guide the operations of the Centre
- submits to the ANU Vice Chancellor:
 - an [Operational Plan](#) at the beginning of each year,
 - an [Annual Report](#) at the end of each year, for presentation to the ANU Council.

The Director and the Community Engagement Coordinator:

- provide the Board with quarterly reports against the Operational Plan, which are included in [Board minutes](#).

GOVERNING PRINCIPLES

The following principles, established by the NCIG Board, govern the operations of the Centre:

Integrity, Trust and Respect

NCIG acts with integrity, builds trust and behaves ethically. NCIG gives respect and strives to earn it in return.

Transparency

Transparent and accountable processes and clear lines of responsibility, accountability, reporting and communication are integral to NCIG operations.

Indigenous Governance

Indigenous Australians play the central role in NCIG's governance and decision making.

Indigenous Engagement

NCIG is committed to long-term engagement with individuals, families, communities and organisations based on respect for the principles and values of Aboriginal and Torres Strait Islander cultures.

International Best Practice

NCIG is committed to the development and implementation of international best practice in all its operations to ensure outcomes of the highest quality and value.

Research Excellence

NCIG is committed to conducting and enabling research of the highest quality.

Confidentiality, Privacy and Security

NCIG protects the privacy of participants and the confidentiality and security of data and information about participants.

POLICY FRAMEWORK

Under Section 8 of the Statute, NCIG must comply with Commonwealth laws that apply to the University and statutes, rules, orders and policies of the University.

In accordance with Section 12(3)(b) of the Statute, the NCIG Board has made [additional policies](#) in relation to:

1. Indigenous Community Engagement
2. Ethical Oversight
3. Additions to the Collection

4. Access to the Collection for Research
5. Media and Communication
6. Publication
7. Conflict of Interest

THE NCIG BOARD'S ROLE IN ETHICAL OVERSIGHT

Under the NCIG Board Policy on Ethical Oversight:

- The NCIG Board approves an ethics protocol for NCIG Research which is also approved by the ANU and other relevant Human Research Ethics Committees (HRECs)
- The NCIG Director reports to the NCIG Board on ethical aspects of NCIG Research
- Proposed variations to the ethics protocol are approved by the NCIG Board
- NCIG does not report or apply for variations to the ethics protocol directly to the ANU and other relevant HRECs.
- Rather, the Chair and Secretary of the ANU and other relevant HRECs have access to relevant NCIG Board papers, which must include reports on ethical aspects of NCIG Research, applications for variations to the Protocol, and Board responses, including questions and concerns raised and the responses to these.

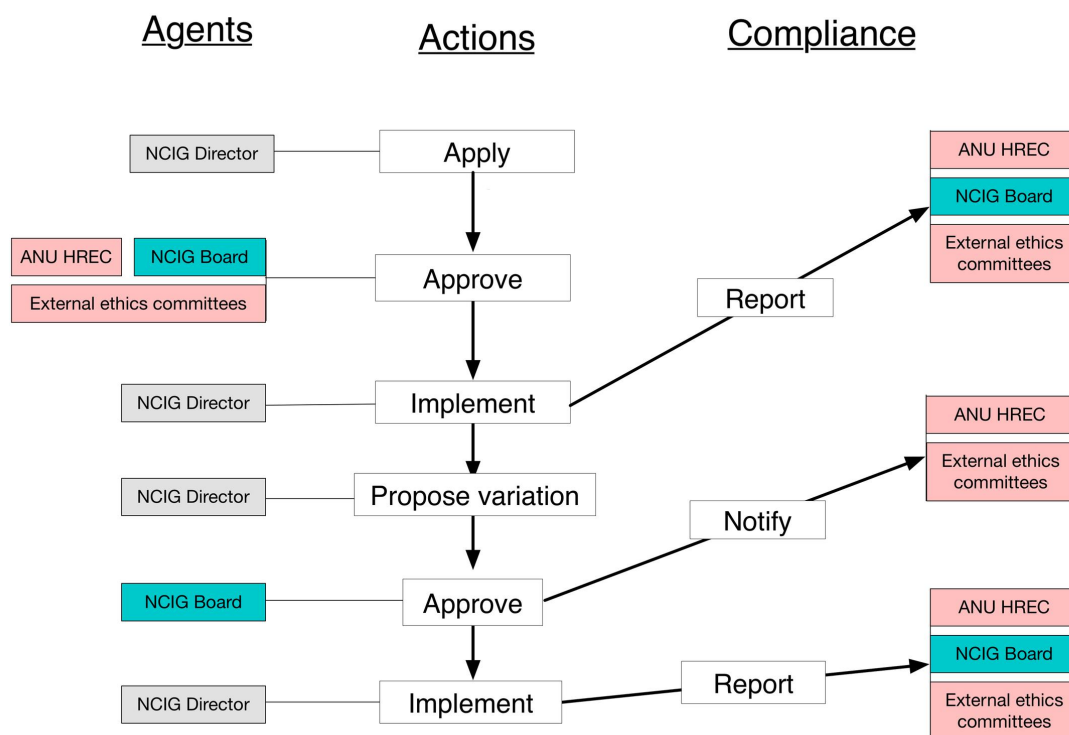


Figure 2. NCIG ethics protocol approval and reporting arrangements.

THE SCOPE OF THE NCIG ETHICS PROTOCOL

- This ethics protocol applies only to **NCIG Research**, which is undertaken as part of NCIG's internal operations that has the primary objective of improving NCIG's ability to fulfil its functions as described in the Statute.
- External collaborators on NCIG Research (Figure 3) must agree in writing to comply with the NCIG Statute and NCIG policies, including the policy on ethical oversight.
- For researchers outside the ANU, formal agreements between ANU and their host institutes are required to ensure full accountability to the NCIG Board.
- NCIG applies to jurisdictional Aboriginal and Torres Strait Islander Health Ethics Committees for ethics protocol approval for NCIG research, as required.
- The NCIG ethics protocol does not apply to **External Research Projects**, which address specific research questions through access and use of material in the NCIG Collection.

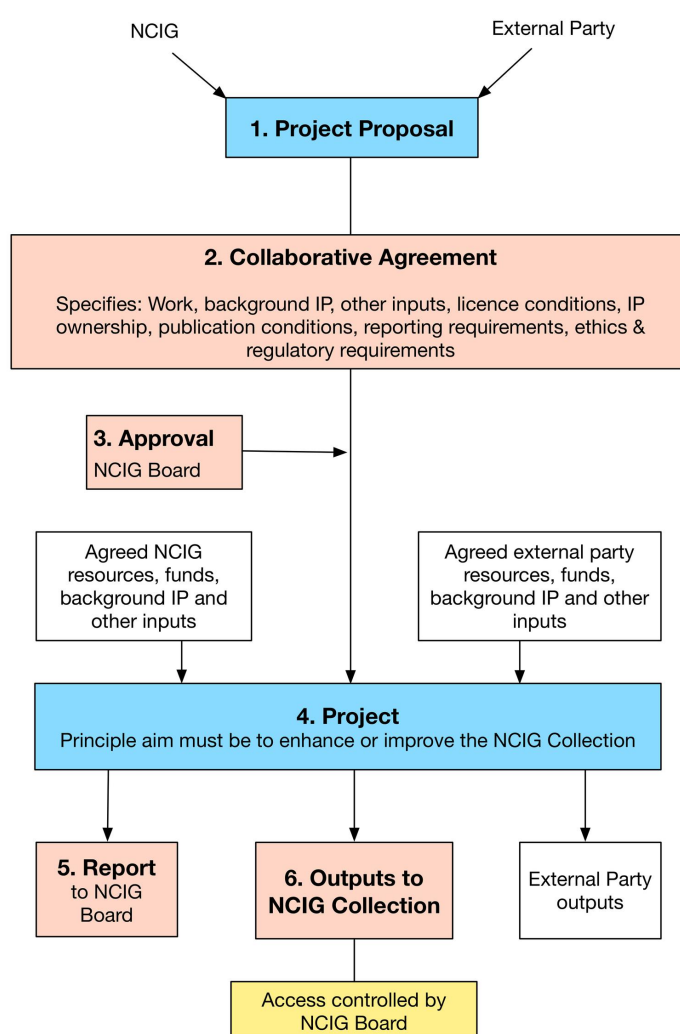


Figure 3. Preparation, approval and reporting requirements for NCIG Research

4. Management

The NCIG Director is a member of ANU staff and cannot be a member of the Board. The Director is responsible for:

1. Supporting the Board as the custodian of the Collection and in the exercise of its other functions under the Statute
2. Managing the operations of the Centre in accordance with Commonwealth laws that apply to the University; statutes, rules, orders and policies of the University; the operational plan prepared and varied, from time to time, by the Board; and policies approved by the Board in relation to the Collection.

The NCIG Director provides quarterly reports to the NCIG Board on progress in implementing the Board's Operational Plan.

NCIG staff report to the Director.

NCIG DIRECTOR

[Professor Simon Easteal](#)

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Qualifications

BSc (Hons), Zoology. University of St Andrews
PhD, Genetics. Griffith University
MBA. Australian National University

Role in NCIG research

Professor Easteal has overall responsibility for the operation of NCIG as directed by the Indigenous-majority Board through an annual Operational Plan, providing the Board with quarterly reports and supporting the Board in the preparation of Annual Reports to the Vice Chancellor. He is responsible to the Board for the conduct of staff, students, collaborators and consultants engaged in NCIG's operations.

NCIG STAFF AND STUDENTS PARTICIPATING IN NCIG RESEARCH

[List of current and past staff and students](#)

OTHER INVESTIGATORS PARTICIPATING IN NCIG RESEARCH

NCIG collaborates with outside investigators who have specialist expertise that is needed for the Centre's work.

[List of current and past collaborators](#)

5. NCIG Research

AIMS AND SCOPE

- NCIG's mission is to work with Indigenous communities under Indigenous governance to create an enduring source of genomic information that will improve the individual and population health of Aboriginal and Torres Strait Islander Peoples.
- NCIG undertakes research as part of the Centre's internal operations (referred to as NCIG Research), which has the primary objective of improving NCIG's ability to fulfil its functions described in the Statute, as determined by the Board.
- NCIG Research aims to:
 - improve the Centre's community engagement process;
 - improve the quality, utility and potential benefits of material in the NCIG Collection;
 - improve systems and processes for managing material in the Collection;
 - address legal, regulatory, governance, policy and/or ethical aspects of NCIG operations;
 - address social, political and/or cultural aspects of NCIG operations.

[Current NCIG Research projects](#)

[Current NCIG development projects](#)

THE NCIG COLLECTION (FIGURE 4)

The NCIG Collection consists of:

1. Biological samples collected from Indigenous Australians
2. Genomic and related data associated with these samples
3. Documents and Records associated with these samples

which are managed as follows:

1. Biological Samples

Biological samples in the NCIG Collection are managed as described in:

[The Biorepository Manual](#)

documented in:

[The Biorepository 'Lab Book'](#)

2. Data

Managed as described in:

[The Data Management Plan](#)

[The Data Management Manual](#)

documented in:

[The Data Management 'Lab Book'](#)

3. Documents and Records

Managed as described in:

[The Document and Record Management Manual](#)

documented in:

[The Document and Record Management 'Lab Book'](#)

NCIG has a comprehensive [library of standard operating procedures \(SOPs\)](#) that guide operations in the following areas:

- Administration
- Biorepository management
- Community engagement
- Data management
- Ethical oversight
- Records and document management
- Research management

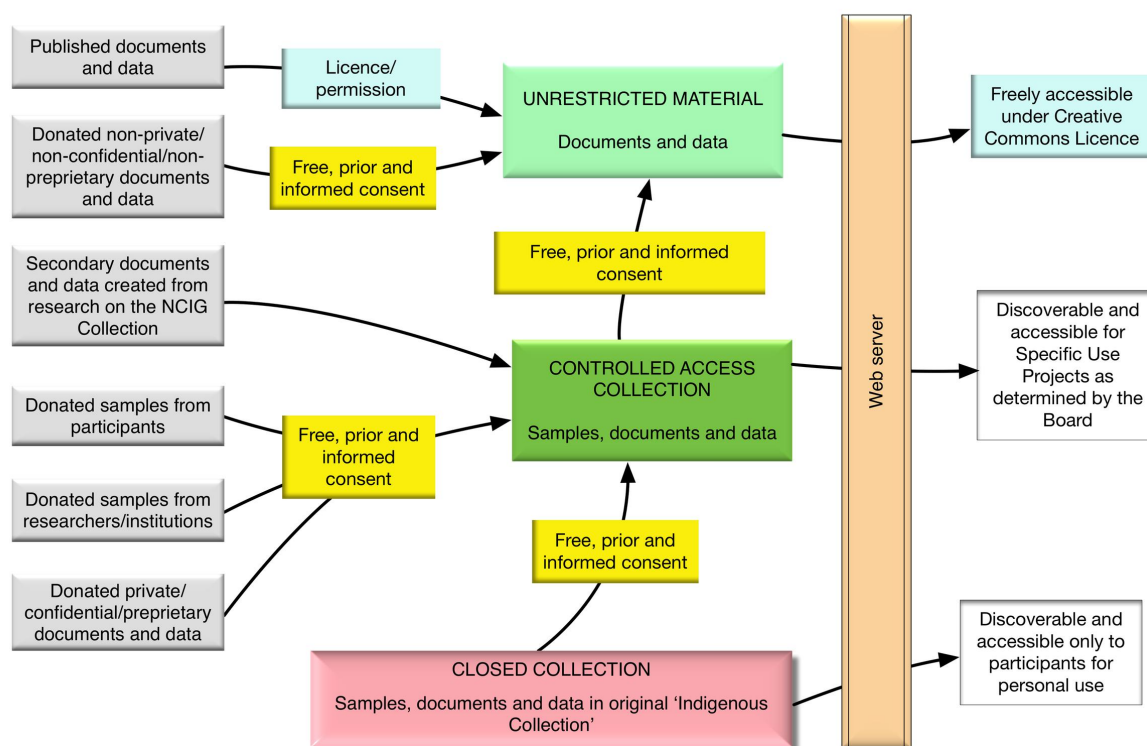


Figure 4. Informed consent for access and use of material in the NCIG Collection showing: sources of material in the Collection; processes for which informed consent is required; means of access to material in the Collection.

METHODOLOGY

The methodologies used for NCIG Research are detailed in descriptions of each [current NCIG Research project](#). Auditable, version-controlled lab books are maintained for each project, ensuring that the implementation of methods is transparent.

NCIG also undertakes software and other development projects that relate to community engagement and to the management of the Collection. Methodologies used are similarly detailed in descriptions of [current projects](#).

PARTICIPANTS

NCIG is specifically focused on Aboriginal and Torres Strait Islander Peoples. Participants are adults. They include people in the following categories:

- Healthy members of the community
- Members of specific community groups
- Members of socially disadvantaged groups
- People whose primary language is other than English
- Aboriginal and Torres Strait Islander peoples
- Donors of human tissue samples
- People highly dependent on medical care who may be unable to give consent

Potential participants are identified in one of the following ways:

1. The person has previously provided a sample that is in the NCIG Collection.
2. The person has expressed an interest in participating in NCIG.
3. The person has previously provided a sample to another project and has expressed an interest in having that sample (and possibly data derived from the sample) included in the NCIG Collection.

The exact number of participants will depend on the number of people providing consent and the availability of funds. The initial aim is to involve ~5,000 participants over 5 years.

LANGUAGE AND LITERACY

Research is conducted in English.

Some participants do not have a good understanding of English, and some participants have low literacy levels.

To ensure that consent is informed, NCIG:

1. Uses official translation services where these are available. Translators are required to sign confidentiality agreements.
2. Works with local community organisations to ensure that well informed local community members are able to act as translators and who can answer questions about the project.
3. Communicates information about the main aspects of the project to potential participants using video animation in addition to providing them with the Information Sheet and answering their questions and addressing their concerns, using translators when necessary.

NCIG will translate the information sheet and consent form into local languages when necessary and as funding permits.

6. External Research Projects

[Current external research projects](#)

One of NCIG's primary functions is to enable access to material in its Collection for research purposes.

The NCIG Board policy describes the requirements for accessing material in the NCIG Collection (Figure 2):

1. Free, prior and informed consent from donors is required for restricted material in the NCIG Collection to be made available for use for external research projects.
2. Researchers, including NCIG staff, wishing to access and use material in the NCIG Collection for external research projects must [submit an application](#) to NCIG.
3. Applications to access and use material in the NCIG Collection are made in confidence.
4. [The Collection Access Committee](#) reviews applications and recommends to the Board that proposals are either: approved, rejected or reconsidered following specified amendments.
5. Final decisions on application approval are made by the NCIG Board.
6. The Collection Access Committee may seek confidential advice from members of the NCIG [Research Advisory Committee](#) on specific aspects of an application.
7. External researchers whose applications are successful must agree in writing to comply with the NCIG Statute and NCIG Board policies. For researchers outside the ANU, formal agreements between ANU and their host institutions are required to ensure full accountability to the NCIG Board.
8. External research projects require and must comply with separate ethics protocols approved by the appropriate institutional and jurisdictional ethics committees.

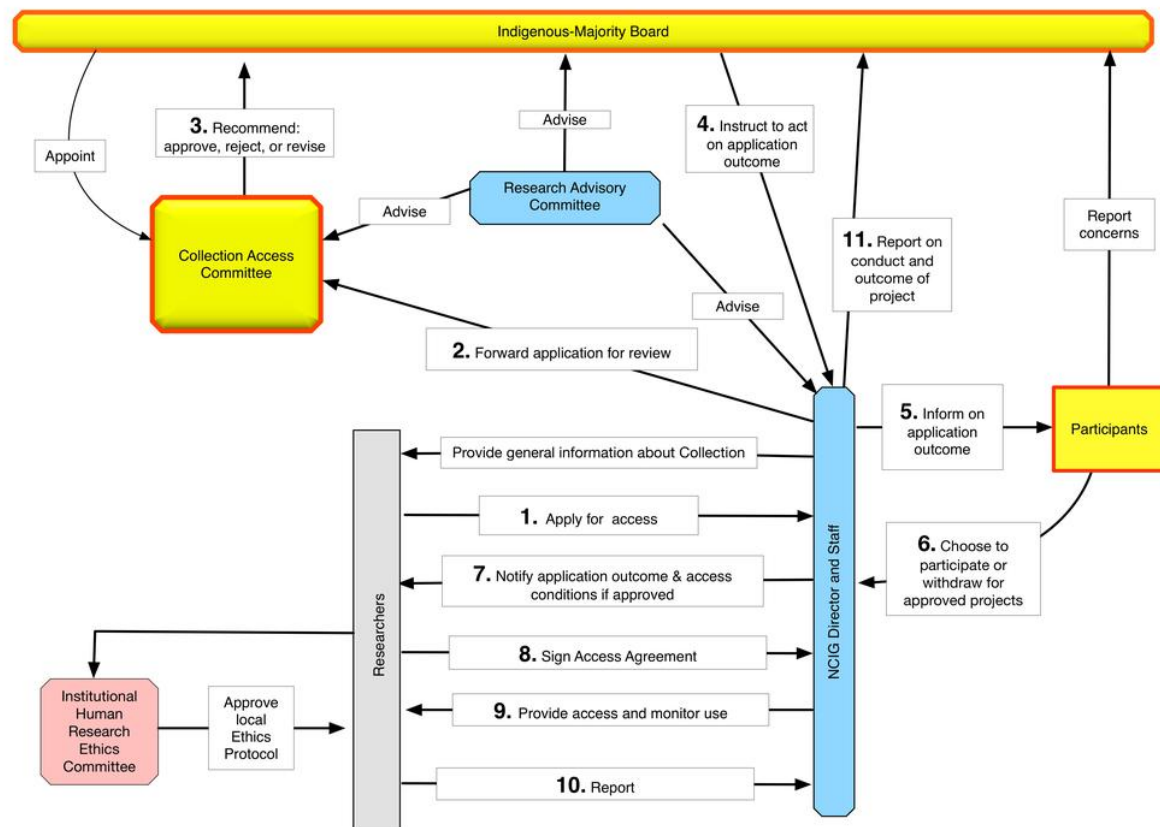


Figure 5. Process for accessing and using material in the NCIG Collection for specific research projects.

7. Monitoring the conduct and progress of the project

Ethical conduct is enhanced through high levels of transparency and accountability in all of NCIG's operations.

- The NCIG Board has a statutory requirement to provide the ANU Vice Chancellor with an annual operational plan for the Centre and with an annual report on the operations of the Centre, which is presented to the ANU Council.
- The NCIG Director and the Community Engagement Coordinator provide quarterly reports to the NCIG Board against the operational plan.
- Internally, progress is monitored through a series of weekly meetings focused on: general administration, collection management, development projects and NCIG Research projects.
- NCIG maintains auditable and version-controlled [records](#) of the following activities associated with developing and managing the NCIG Collection:
 - Community outreach
 - Community visits to NCIG
 - Engagement with Indigenous organisations
 - Biorepository management
 - Document and record management
 - Data management
 - Development projects

- NCIG Research projects
 - Management of External Research Projects
- NCIG keeps a [log of ethics incidents](#), which are reported to the NCIG Board.

8. Cultural and Social Considerations & Sensitivities

NCIG's approach to managing cultural and social considerations and sensitivities associated with its operations are detailed in the [Community Engagement Manual](#).

9. Incentives

Participants are not paid. The only incentive that is offered is the opportunity to participate in the project and contribute to the benefits it delivers.

10. Benefits

DIRECT BENEFITS FROM NCIG RESEARCH

The principle benefit from NCIG Research is to maximise the value of its Collection as a resource for research to benefit Aboriginal people.

Immediate benefits arising from NCIG research align with NHMRC Indigenous research excellence criteria.

COMMUNITY ENGAGEMENT

- [NCIG's Community Engagement Program](#) is central to the Centre's operations.
- The Program is conducted as described in the [Community Outreach Manual](#).
- NCIG employs a full-time Indigenous Community Engagement Coordinator and actively engages with specific communities in the Northern Territory, Queensland and Western Australia.
- NCIG's commitment to long-term, ethical engagement with individuals, families and communities ensures:
 - Community participation in NCIG Operations, including local employment of staff, where possible
 - A collaborative and equitable approach to research based on shared values
 - Local relationships that ensure an ongoing shared understanding of NCIG Operations and of how they affect and are affected by local cultural practices and circumstances
 - Respect for participant and community requirements, wishes and preferences for how engagement with NCIG is conducted, including culturally right ways of decision-making.

- NCIG actively seeks to employ Indigenous Australians whenever appropriate, to develop relationships with Indigenous people, and to work with Indigenous organisations at national, regional and local levels.

A high level of Indigenous involvement ensures:

- Knowledge and awareness of the cultures and values of Aboriginal and Torres Strait Islander peoples.
 - Respect for the principles and values of Aboriginal and Torres Strait Islander cultures.
 - The knowledge, understanding and expertise needed to maintain long-term ethical relationships with Participants and Indigenous communities.
 - Indigenous input into the design and conduct of NCIG operations.
 - Culturally appropriate conduct of NCIG operations.
 - Outcomes that are valued by Indigenous peoples and that have benefits that are in line with their priorities.
- Placing research participants at the centre of medical research in which they are involved – so-called ‘participant-centric research’ – is emerging as a requirement for success in major global research initiatives around the world.
 - In this context, the benefits of NCIG’s ability to achieve long-term dynamic engagement with participants and communities extends beyond the Indigenous communities where it is being developed. This is just one important way in which Indigenous research can provide a model for the conduct of research in the broader community.

SUSTAINABILITY AND TRANSFERABILITY

[NCIG's Sustainability and Transferability Strategy](#)

- NCIG has established a governance structure and operational model that ensure the persistence of the resources that it creates.
- NCIG extends the reach of investigators working in many fields relevant to Indigenous health, enabling them to better incorporate genomic research in their work, thereby enhancing its significance and potential.
- NCIG also provides a model of community engagement that may be extendable to other areas of advanced biomedical research, thereby expanding the range of research in which Indigenous Australians can participate and benefit from without risking social or cultural harm.

BUILDING CAPABILITY

[NCIG's Capability Building Strategy](#)

- NCIG builds capability in three ways.
 - NCIG's [Outreach Program](#) provides access to knowledge about genome research to Indigenous students and community members.
 - NCIG's model of dynamic engagement provides a means of ongoing engagement between researchers and participants, enabling reciprocal exchange of knowledge and information.
 - NCIG employs local people as research assistants and to play other roles, who gain an enduring understanding of this field of research as well as experience and expertise that they can pass on to other community members and broaden future employment prospects.

- Research translation activities including the development of health promotion approaches that enable Indigenous Australians to better understand the role of genomics in health and medical research, in health care and in medical practice.
- Providing advice on making new knowledge available to Aboriginal people in a culturally safe and meaningful way. Managing and developing health and medical research evidence, including linking with international Indigenous health research.

POTENTIAL BENEFITS FROM EXTERNAL RESEARCH PROJECTS

External Research Projects are approved if they meet the criteria established by the NCIG Board. In deciding whether to approve projects, The NCIG Board take advice from the [Collection Access Committee](#).

Potential benefits from external research projects include:

1. Health and medical benefits

- NCIG provides reference data about genome variation in Indigenous populations to enable variation associated with health and disease to be appropriately interpreted.
- Genomic variation is very similar in most human populations, but there can be important differences, particularly of rare genetic variants. Genes that contribute to specific diseases may differ between populations, sometimes because of exposure to different environmental factors. In some genes there are many different rare mutations that make similar contributions to disease with each of the mutations confined to related individuals in specific regions.
- The role of genome function and variation in health and disease in Indigenous Australians cannot be understood solely from studies of European populations. Knowledge of genome variation in Indigenous populations is also needed. NCIG's principle objective is to enable that knowledge to be created through the creation of its reference database and through the research that this resource enables.
- Researchers will be able to ensure that associations they find between genome variation and disease are due to the disease and are not instead a result of the varying ancestries within the study population.
- Indigenous participants and communities may decide that the genomic data in the NCIG Collection is used to: provide information to assist with medical diagnosis and to guide treatment of disease; identify people who are carriers of genetic disorders, or who are at elevated or reduced risk of disease. They may decide that data is used for research aimed at new discoveries about how genetic variation causes or protects against disease and causes people to respond differently to drugs and other forms of therapy.
- Research using the NCIG Collection could lead to new discoveries about the way genetic differences between people's genomes influence how their life history and environment affect their health and cause epigenetic changes to the structure of their genomes that modify how their genomes function in a way that may affect their health and wellbeing.
- Research could also lead to the development of diagnostic, prognostic and predictive medical tests; new strategies for assessing disease risk; new interventions that prevent or reduce the risk of disease; new drugs and other therapies that can be used to treat or cure disease; new approaches and specific devices for monitoring health, and monitoring the effectiveness of preventative and therapeutic health interventions.
- In communities where NCIG has commenced engagement activities, family members of original donors and other community members have expressed interest in donating new

samples to the NCIG Collection. In this way, the size of the NCIG Collection may be extended to include up to five generations of individual families.

- If participants, their families and other community members wish to participate in research that links genomic information to health and medical records, the scope of research aimed at understanding the causes of disease will be further extended.

2. Reconnecting families

- The NCIG Collection may be useful in finding lost family connections or confirming uncertain family relationships. Reconnecting with family in this way may have beneficial effects on the health and wellbeing of Stolen Generations and other people whose family connections have been lost.
- Indigenous families and communities may wish to use the NCIG genome database as a reference for people who wish to trace their genealogical roots from their own genome sequence information. Anticipating a demand for such services, NCIG will establish best-practice guidelines for genealogical interpretation of genomic data for Indigenous Australians.

3. Returning ancestral human remains to country and to family

- Many of the ancestral remains of Indigenous Australians still held in museums, hospitals and other institutions both in Australia and elsewhere cannot be appropriately repatriated because information about their provenance is lacking.
- Indigenous communities may wish to use the NCIG Collection to help identify the location and even the family of origin of ancestral human remains that have been removed from Aboriginal and Torres Strait Islander communities, particularly in cases where the origins, or provenance, of the remains cannot otherwise be accurately determined.
- Genome data in the NCIG Collection could provide a source of reference data against which genome sequence data from ancestral remains could be compared. By matching genome sequences from specific human remains with those in the different communities represented in the database, it may be possible to identify the geographical origin of the remains. In some cases, where the database is sufficiently complete, it may even be possible to identify living descendants of the people whose remains are being repatriated. In this way the NCIG Collection could help to ensure that ancestral human remains are repatriated to the country where they belong.

4. A richer understanding of Australia's deep history

- Indigenous communities may wish for material in the NCIG Collection to be used for research aimed at understanding the deep historical connections among Aboriginal peoples from different parts of Australia and between Aboriginal and Torres Strait Islander peoples, complementing traditional knowledge and archeological evidence.
- Research could help to reveal the great diversity of peoples who are Indigenous to Australia, complementing traditional knowledge and reflecting the diversity of languages revealed by linguistic research. In this way the NCIG Collection would complement traditional beliefs with new ways of understanding the long history of Australia's people.
- Research could complement traditional knowledge and beliefs about the deep historical connections between Aboriginal and Torres Strait Islander people and people in nearby places like Papua New Guinea and Indonesia and people from other parts of the world.
- In these ways, NCIG's Collection may contribute to a much richer understanding of the richness, depth and dynamic nature of Australia's long human past.

11. Risks

1. PHYSICAL HARM

Potential risks

- There is no physical risk to providing a spit sample.
- There is a small risk of bruising, infection or fainting when providing a blood sample.

Risk management

- Blood is collected by qualified and experienced staff.

2. PSYCHOLOGICAL AND SOCIAL HARM

Potential risks

- Documents and data in the NCIG Collection may reveal sensitive information that may cause participants to feel distress, guilt, anger or embarrassment.
- Documents and data may reveal information that could cause damage to participants' social networks or relationships, or that could result in discrimination, social stigmatization, or could reveal previously unknown paternity or other family relationships.
- Data may also cause psychological harm if they indicate that participants have an untreatable genetic disease.

Risk management

- NCIG only provides information to participants if they initially indicate that they wish to receive it.
- NCIG ensures that participants who request information are informed about the risk of social harm before the information is released to them.
- NCIG works with communities to establish appropriate ways to communicate personal and sensitive information and follow the advice it receives.
- NCIG provides advice and support to participants who request it and ensures that they have access to ongoing local advice and support.
- For participants who consent to receive medically relevant information, NCIG will provide information about genetic disorders through a doctor. The doctor will be responsible for deciding how to use the information in treating their patient.

3. DEVALUATION OF PERSONAL WORTH

Potential risk

- Research results could be used to support negative views about Aboriginal and Torres Strait Islander peoples.

Risk management

- Indigenous people have a say in the way that research results are described when they are published.

- Indigenous people are involved in preparing plain language reports to accompany the publication of research findings.
- NCIG actively counters media reports or public discussions about published research that portray Indigenous people in a negative way.

4. LEGAL HARM

Potential risk

- NCIG may be required by law to disclose information in the Collection that may be used in evidence against a participant in a court case. For example, police may seek to obtain genetic information from the DNA of a participant to determine whether it matches DNA from a crime scene.

Risk management

- This risk is small because NCIG does disclose the identities of participants and because it is difficult to conceive of a circumstance in which such information would be sought when it could not be lawfully obtained directly from a participant.
- NCIG only provides information of this kind when legally required to do so and after it has explored all available legal options to prevent the information from being released.

RISKS TO NCIG STAFF

Potential risks

- NCIG staff incur risks in travelling to visit communities, which are detailed in the [Community Outreach Manual](#), which also details the approach to risk management.
 - NCIG staff travelling to communities report to a base control officer at regular intervals following a set protocol. These reports are logged and incidents are recorded.
- Risks incurred by NCIG staff in using laboratory and other facilities in the JCSMR building and processes for managing these risks are detailed in the [ANU Health and Safety Management Arrangements](#).

JUSTIFICATION

The Project is ethically justified because its substantial potential benefits greatly outweigh its relatively minor risks, for which management strategies are in place, as indicated above.

12. Informed consent

- Informed consent is be obtained in writing from participants, using the [Participant Consent Form](#).
- NCIG's approach to consent is embedded within the broader community engagement program. It is not treated as a transactional process in isolation.
- Consent is only sought following extensive community consultation and dialogue with all relevant stakeholders in a community.

- In addition to participants and their families, this may include community Elders, Traditional Owners, Councils, Health Organisations and Prescribed Bodies Corporate.
- Consent usually follows several visits to community and sometimes visits by community representatives to NCIG.
- The initial discussion with communities is about how the community would like NCIG to talk to the community.
- NCIG's approach is to follow guidance from the community about how to approach and inform people about NCIG's work and their potential to participate.
- Information is provided through the [Participant Information Sheet](#), a video animation, and lengthy discussion within communities.
- When participants initially indicate that they wish to participate, they are advised to take time to think further about their decision and to discuss it with their families.

Who can give consent?

- Discussions about consent are conducted according to local practice and community protocols. Each community has a different approach, and NCIG is guided by local protocols and the wishes of the community.
- If the donors of samples already in the NCIG Collection are unable to provide consent due to death or incapacity, or because they cannot be located, NCIG consults with their families and community leaders about the proper community protocol.
- A community may decide that a surviving descendant relative should make the decision about consent.
- It may decide that the decision should be made by the head of the family or clan group.
- Alternatively it may decide that community elders should make the decision.
- NCIG follows the protocol specified by the community.
- NCIG only seeks consent if there is general agreement in the community about the approach to be taken.

Dynamic consent

- NCIG continues to visit communities even after all required consents have been obtained to report back progress and findings.
- Ongoing visits enable participants to tell NCIG if they have changed their mind about consent.
- Ongoing visits also enable NCIG to discuss what should happen to a participant's sample or data if they have passed away.
- NCIG follows local community protocols in conducting these discussions.

13. Confidentiality

- Personal information that is collected during the project may be: identified; re-identifiable/coded; or non-identifiable. It is stored in all these forms.
- Recordings of participants are made. Recordings are retained and used beyond the initial transcription/analysis. Personal information is only be published in non-identified form.

- Measures to preserve confidentiality are described in the [Record/Document Management](#) and [Data Management](#) Manuals.

14. Data Storage Procedures

- Data storage procedures, including measures to ensure confidentiality, integrity, privacy, security and protection are described in the:
 - [Data Management Manual](#)
 - [Record/Document Management Manual](#)
- Data is stored indefinitely.
- NCIG's processes relating to confidentiality, integrity, privacy, security and protection are reviewed on a regular basis to ensure compliance with national and international laws, policies, guidelines and best practice standards.

Location of Data Collection

- Data is collected from Indigenous Australians in communities in Western Australia, the Northern Territory and Queensland.
- Data may, in future, be collected from Indigenous Australians in other jurisdictions.
- Data is maintained on secure servers in Australia.

15. Debriefing

- Participants can become distressed when discussing the project if they have unfortunate memories of the time when samples were collected or when they discover that there are samples in the NCIG Collection obtained from relatives or important community members, who have passed away.

As detailed in the [Community Engagement Manual](#):

- NCIG staff provide support and advice when participants become distressed during community visits
- When working in communities, NCIG staff liaise with local health and other organisations, who can provide additional support and counseling if required
- NCIG staff debrief on return from community visits following a set protocol detailed in the [Field Trip Base Control SOP](#).

16. Feedback

- On written request, NCIG provide material to participants who are directly associated with the material, with the exception of information that has implications for their health or healthcare.
- For patients who consent to the return of medically relevant results, NCIG provides these to a doctor. The doctor is responsible for deciding how to use the information in treating their patient.

- When the results relate to genetic diseases, NCIG informs the relevant clinical genetics service.

17. Financial arrangements

SOURCE OF FUNDING AND SUPPORT

- NCIG is supported by funds from institutional, government and philanthropic sources ([Table 1](#))
- ANU has made a substantial strategic financial investment in NCIG ([Table 1](#))
- ANU, through NCIG, does not currently generate revenue through the provision of services or the sale of goods, or the licensing or sale of intellectual property
- Commercial gain from research undertaken on the NCIG Collection is possible but unlikely. Profits generated in this way will be shared with participating Indigenous communities (see below)
- NCIG obtains advice and support, *pro bono*, from outside agencies.
- NCIG, through the ANU, agrees to terms in contracts or agreements with external agencies only when these are consistent with ANU Policies and with the NCIG Statute and Policy Framework.

[List of NCIG funding sources](#)

USE OF FUNDS

Funds received by NCIG are used to:

- pay for the direct costs and expenses of NCIG's operations
- acquire physical assets, such as laboratory equipment, required to conduct NCIG operations.
- pay the indirect costs that ANU incurs in supporting and administering NCIG's operations, as determined by ANU Policy.

FINANCIAL REPORTING

- Under 20(2)(a) of *The Statute* the NCIG Board must include in its annual Operational Plans submitted to the ANU Vice Chancellor, the projected revenue and expenses for the Centre and the Board for at least the plan year.
- The Director provides quarterly statements on revenue and expenditure to the NCIG Board, which are included in Board minutes
- The Board provides annual statements of revenues and expenditure as part of the annual reports it provides to the ANU Vice Chancellor for presentation to the ANU Council.

18. Intellectual Property

NCIG RESEARCH

- ANU, through NCIG, may create intellectual property in the form of symbols, product designs, drawings, literature, art, film, computer programs, trade secrets, confidential information, inventions and new processes, over which it may be entitled to monopoly rights in the form of copyright, moral rights, trademarks, industrial design rights, patents and other forms of intellectual property protection.
- ANU may apply for legal protection of its intellectual property if the NCIG Board decides that doing so is in the best interests of participants and Indigenous communities.
- NCIG Research and other developments within NCIG could lead to advances in preventing, treating and curing disease and in promoting health, and to other beneficial outcomes that may best be realized through commercial development, as is commonly the case in biomedical research.
- In pursuing these potential benefits, ANU may enter into commercial arrangements to obtain income through: licensing agreements between ANU and other parties, fees for services provided by NCIG; royalty fees paid to ANU by other parties.
- The NCIG Board, as custodians of the NCIG Collection, will ensure that ANU only enters into commercial arrangements if NCIG has commercialisation and benefit sharing agreements that are consistent with community wishes.

EXTERNAL RESEARCH PROJECTS

- Researchers or clinicians accessing and using material in the NCIG Collection for specific External Research Projects under an **Access Agreement** may develop Intellectual Property.
- They may obtain income from their Intellectual Property as stipulated in their Access Agreement, which includes provisions for commercialisation and benefit sharing agreements with relevant participants and Indigenous communities.
- Researchers or clinicians accessing the NCIG Collection must notify NCIG before engaging in any activities or conducting any discussions that are intended to lead to the commercial development of intellectual property or other assets arising from research on the NCIG Collection including:
 - Applying for any form of legal protection for Intellectual Property or other assets, including patents or companies limited by shares
 - Entering into licensing agreements or other arrangements to receive income in exchange for access to Intellectual Property or other assets.
 - Selling, assigning or otherwise disposing of Intellectual Property or other assets.
- Researchers or clinicians accessing the NCIG Collection must adhere to the benefit sharing conditions of their Access Agreement.

19. Benefit sharing

[NCIG's Benefit Sharing Strategy](#)

- NCIG does not operate with a primary intent of deriving profit from income or assets.
- The main benefits of participation, detailed above, are likely to be non-financial
- If profit is derived from income and assets arising from NCIG Research, including intellectual property, it will be shared with participating Indigenous communities under benefit sharing agreements.
- Benefits will be in the form acceptable to the communities involved and in a way that is proportional to the contributions to the creation of commercial value.
- Payments will not generally be made to individual participants because:
 - an individual cannot ethically obtain financial compensation for the use of his or her body parts
 - it may not be possible to identify individual contributions when commercial value is created through research carried out on data from many individuals

20. Conflict of Interest

- Section 17 of the *NCIG Statute* stipulates the duty of Board members to disclose interests, and the consequences of their having interests.
- The [ANU Policy on Conflict of Interest and Commitment](#) applies to NCIG personnel who are ANU staff or students.
- The [NCIG Board policy on conflict of interest](#) applies to NCIG Board Committee members who are not ANU employees. This policy largely follows the ANU policy on conflict of interest and commitment.
- Actual, potential or perceived conflicts of interest must be declared to the committee Convenor or the Board Chair, who decide what, if any, action should be taken.
- Conflict-of-interest declarations and any resulting action are reported to the Board for noting and included in the minutes of Board meetings.

21. Definitions

Access Agreement means a legally binding agreement between an external party and the ANU that specifies the terms and conditions for access to, and use of, material in the NCIG Collection.

the Centre means National Centre for Indigenous Genomics.

Closed Collection is the part of the NCIG Collection containing containing private, confidential or proprietary information that cannot be accessed for research purposes.

the Collection (also **the NCIG Collection**) means biological samples, documents/records and data held by NCIG, as specified in Part 2. 5 of the Statute.

Controlled material means material in the NCIG Collection that is private or confidential, and accessible for specific use only under an Access Agreement following approval by the NCIG Board.

Cultural competence means the ability to interact effectively with people across different cultures.

External Research Project means a research project that addresses a specific research question through access and use of the NCIG Collection. The NCIG Ethics Protocol does not apply to external projects. External Research Projects must be approved by the NCIG Board. They are not covered by the NCIG Ethics Protocol and require separate ethics approval.

Human Research Ethics Committees (HRECs) are established by organisations in Australia to review research proposals involving human participants to ensure that they are ethically acceptable and in accordance with relevant standards and guidelines.

Jurisdictional ethics committee means an HREC that has the role of assessing research proposals affecting the health and wellbeing of Aboriginal people and communities in an Australian jurisdiction, and which is registered with the NHMRC. NHMRC registration means that the institution(s) that established the HREC notifies NHMRC of the HREC's existence and provides a signed declaration that the HREC will comply with the National Statement on Ethical Conduct in Human Research, 2007 (National Statement) and any revisions made to it.

Material means biological samples, documents and data.

NCIG Research means research undertaken as part of NCIG's internal operations that has the primary objective of improving NCIG's ability to fulfil its functions as described in the Statute.

NCIG Personnel means NCIG Board members, NCIG staff, members of NCIG Board committees, and students, interns, volunteers, consultants and collaborators working with NCIG.

NCIG Statute (also **the Statute**) means the *National Centre for Indigenous Genomics Statute 2016*.

Research means "work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artifacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction". *[This definition of research is used in The British Research Assessment Exercise and quoted in the National Statement on Ethical Conduct in Human Research 2007].*

Sample means biological material taken from a person's body for a research or medical purpose, such as solid tissue, blood or cells contained in saliva and any separated component (such as red blood cells, white blood cells and plasma in the case of blood) and any derived component such as protein, DNA or RNA.

22. Supporting Documentation

INFORMED CONSENT

1. [Participant information sheet](#)
2. [Information video animation](#)
3. [Participant consent form](#)
4. [Online Participant consent form](#)
5. [Participant details form](#)
6. [Translator confidentiality form](#)

GOVERNANCE, POLICY, PLANNING AND REPORTING

1. [NCIG Statute](#)
2. [NCIG Governance Framework](#)
3. [NCIG Strategic Plan \(2017-2020\)](#)
4. [Annual Report \(2017\)](#)

CONTACT

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Contact the Centre Administrator & Board Secretary to request access to the following additional documents:

1. Biorepository Manual
2. Biorepository Management 'Lab Book'
3. Board Agendas
4. Board Minutes
5. Board Handbook
6. Community Engagement Manual
7. Community Engagement Reports
8. Current NCIG Research Projects
9. Current External Research Projects
10. Data Management Manual
11. Data Management 'Lab Book'
12. Ethics Incidents Reports
13. Induction Manual
14. Operational Plan
15. Record/Document Management Manual
16. Record/Document Management 'Lab Book'
17. Standard Operating Procedure Library

RELATED ETHICS RESOURCES

15. [National Statement on Ethical Conduct in Human Research \(2007\)](#)
16. [Australian Privacy Principles](#)
17. [Australian Code for the Responsible Conduct of Research, 2018](#)