

NCIG Governance Framework

Background

The National Centre for Indigenous Genomics (NCIG) is established as a body within the Australian National University (ANU) by *The National Centre for Indigenous Genomics Statute (2016)*. This Statute provides ANU with the legal foundation to support NCIG.

The Statute commits ANU to ensuring that:

- the Collection is under Indigenous custodianship
- there is proper engagement with Indigenous people and the communities from which samples, records and data are collected
- appropriate consents are obtained for research using the Collection.

In accordance with the Statute, the ANU Council delegates the custodianship of the NCIG Collection to the NCIG Indigenous-majority Board. As custodian, the Board is responsible and accountable for the management, use, and appropriate addition of material to the Collection.

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.

Governing Principles

NCIG operates in accordance with the principles set out in:

- the National Health and Medical Research Council (NHMRC): Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research
- the Australian Institute for Aboriginal and Torres Strait Islander Studies (AIATSIS): Guidelines for Ethical Research in Australian Indigenous Studies
- The United Nations Declaration on the Rights of Indigenous Peoples.

The following principles are of paramount importance in ensuring that the Centre fulfils its purpose under the Statute.

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.

Sources

The Australian Code for Responsible Conduct of Research, 2018

The National Statement on Ethical Conduct in Human Research (2007)

The Australian Institute of Aboriginal and Torres Strait Islander Studies Guidelines for Ethical Research in Australian Indigenous Studies (2012)

The National Centre for Indigenous Genomics Statute (2016)

United Nations Declaration on the Rights of Indigenous Peoples

Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003)

Related material – ANU Policies

Responsible conduct of research
Code of research conduct
Intellectual property
Privacy

NCIG Board Policies

1. INDIGENOUS COMMUNITY ENGAGEMENT

Purpose

In accordance with the Statute, the Australian National University is committed to ensuring that there is proper engagement with Indigenous people and communities about use of the Collection for research, and that specific and appropriate consents are obtained for research using the Collection.

Overview

This policy specifies how NCIG engages with Indigenous communities.

Scope

This policy applies to the NCIG Board, Committees of the Board, NCIG staff and to all other parties who participate in NCIG's Community Engagement Program.

Policy statement

1. NCIG visits communities only when invited to do so for purposes that support NCIG's functions under the Statute. These include:
 - obtaining guidance on the Board's custodianship of the Collection
 - informing community members and organisations of the existence of the Collection
 - seeking guidance from community members and organisations on how to engage with communities
 - explaining how material in the Collection might be used in research to benefit Aboriginal and Torres Strait Islander peoples
 - explaining other potential uses of the Collection that may benefit Indigenous Australians
 - seeking consent to make material in the Collection available for research
 - receiving feedback on NCIG's purpose, conduct and processes
 - providing ongoing information and explanation about the work of the Centre and use of material in the Collection.
 - Necessary permits and approvals must be obtained before community visits.
2. The Indigenous Community Engagement Coordinator has overall responsibility for NCIG's community engagement program and provides quarterly reports to the Board on the conduct and progress of the program.
3. People representing NCIG in communities must follow the Community Engagement Manual. They must complete the specified training and induction requirements that include, at a minimum, Cultural Competence training and briefing on relevant community protocols.

Related material

- ANU Policy: Work health and safety
 - NCIG Community Engagement Manual
 - ANU Procedure: Fieldwork health and off-campus work safety
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2. ETHICAL OVERSIGHT OF RESEARCH

Purpose

All research involving the NCIG Collection must comply with The National Statement on Ethical Conduct in Human Research.

The NCIG Board provides ethical oversight of NCIG Research, which complies with the NCIG Ethics Protocol.

The standards set in the NCIG Ethics Protocol apply to External Research projects. External Research projects must also comply with separate ethics protocols approved by the appropriate institutional and jurisdictional ethics committees.

Overview

This policy specifies how ethical oversight is provided for NCIG Research and for External Research projects.

Scope

This policy applies to the NCIG Board, Committees of the Board, NCIG staff, outside parties collaborating on NCIG Research, and researchers conducting External Research projects.

Policy statement

1. NCIG Research requires the approval of the ANU Human Research Ethics Committee (HREC), the NCIG Board, and appropriate jurisdictional Aboriginal and Torres Strait Islander health ethics committees.
2. Proposed variations to the ethics protocol are approved by the NCIG Board and the ANU HREC. They may also require approval by jurisdictional ethics committees.
3. The NCIG Director reports to the NCIG Board on ethical aspects of NCIG Research.
4. External Research projects must comply with separate ethics protocols approved by the appropriate institutional and jurisdictional ethics committees which must, at a minimum, meet the standards set by the NCIG Ethics Protocol.
5. External collaborators on NCIG Research must agree in writing to comply with the NCIG Statute and NCIG policies.
6. For researchers outside the ANU, formal agreements between ANU and their host institutes are required to ensure full accountability to the NCIG Board.

3. ADDITION TO THE COLLECTION

Purpose

Under the NCIG Statute a function of the NCIG Board is to approve policy for the addition of material to the

Collection. The addition of material to the Collection is a core activity, fundamental to the Board's vision that the Centre will be a trusted and enduring national resource for Indigenous genomics research.

Overview

This policy describes requirements for adding samples, documents, records and data to the NCIG Collection.

Scope

This policy applies to the NCIG Board and committee members, staff, and to external parties seeking to add material to the NCIG Collection.

Policy statement

1. NCIG acquires new samples:
 - directly from donors with free, prior and informed consent in accordance with the NCIG Ethics Protocol
 - from other institutions or from researchers within ANU when free, prior and informed consent has been obtained for the deposition of the samples in the NCIG Collection, in accordance with the NCIG Ethics Protocol.
2. Newly acquired samples become part of the NCIG Collection. These are stored, managed and used in accordance with the NCIG Statute and Board Policies.
3. NCIG generates and acquires records and documents through its custodianship and management of the Collection. Generated and acquired records and documents are stored, managed and used in accordance with the NCIG Statute and policies.
4. Records and documents are generated when the Collection is accessed and used for approved research purposes. Copies of records created in conducting research on the NCIG Collection must be deposited in the Collection.
5. NCIG will generate, and may acquire, genomic and other data.
6. Copies of data resulting from laboratory and bioinformatics analysis of material in the Collection by service laboratories and researchers must be deposited in the NCIG Collection.
7. NCIG may acquire unpublished genomic data from other institutions or from researchers within ANU when free, prior and informed consent has been obtained for its deposition in the Collection, in accordance with the NCIG Ethics Protocol.

Related material

- ANU Policy: Collection, storage and disposal of human tissue in research
- ANU Policy: Collections
- ANU Procedure: Collections
- NCIG Ethics Protocol (ANU HREC)

4. ACCESS TO THE COLLECTION FOR EXTERNAL RESEARCH PROJECTS

Purpose

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

Overview

This policy describes requirements for accessing and using material in the NCIG Collection for research purposes.

Scope

This policy applies to researchers, including NCIG staff, seeking to access and use Controlled material in the NCIG Collection for External Research projects. The policy does not apply to research carried out as part of NCIG's internal operations (NCIG Research).

Policy statement

1. Free, prior and informed consent from donors is required for Controlled material in the NCIG Collection to be made available for use for external research projects.
2. Researchers, including NCIG staff, wishing to access material in the NCIG Collection for external research projects must submit an application to NCIG.
3. Applications to access 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 must comply with separate ethics protocols approved by the appropriate institutional and jurisdictional ethics committees which must, at a minimum, meet the standards set by the NCIG Ethic Protocol.

Related material

- ANU Policy: Collections
- ANU Policy: Records and archives management
- ANU Policy: Collection, storage and disposal of human tissue in research
- ANU Procedure: External Project funding and agreements
- ANU Procedure: Collections
- ANU Procedure: Records management

5. MEDIA AND COMMUNICATIONS

Purpose

This policy ensures that NCIG communicates clear and consistent messages to the media and the general public.

Overview

This policy describes how NCIG communicates with the media and the general public.

Scope

This policy applies to NCIG Board and committee members, staff, collaborators on NCIG Research, and external researchers. It covers communications with external news and current affairs media (broadcast, electronic and print), and with the general public.

Policy statement

1. NCIG responds to appropriate and reasonable media enquiries accurately and in a timely manner to help promote public understanding of NCIG's purpose and activities.

NCIG Spokesperson

2. Media enquiries about NCIG received by Board members must be referred to the Board Chair or Deputy Chair, or if the Chair or Deputy Chair is unavailable, to the Director.
3. Media enquiries about NCIG received by NCIG staff and external collaborators must be referred to

the Director. If the Director is unavailable, enquiries are referred to the ANU Strategic Communications & Public Affairs Department (SCAPA).

4. SCAPA must be notified of all media appearances/interactions, preferably before the event.

Public enquiries

5. NCIG will respond to enquiries from members of the public, and representatives of external bodies and groups in a timely and helpful manner.

Written communication materials

6. Written materials (for example, letterhead, business cards, banners, fliers, information sheets, email address blocks, conference posters) will be co-branded with an approved version of the NCIG logo and the ANU logo.

Compliance with ANU policies and procedures

7. SCAPA and the ANU Marketing Office assist NCIG in its public communications.
8. NCIG will conduct communication and marketing in compliance with ANU policies and procedures except where differences in approach are required in order for the Board to properly exercise its responsibilities under the NCIG Statute.

External researchers

9. Researchers working on projects approved by the Board are able to comment on and promote the outcomes of their research projects within the bounds of their project proposal, Access Agreement and their approved Ethics Protocol.

Related material

- ANU Policy: Academic expertise and public debate
- ANU Policy: Use of University name and insignia
- NCIG Operations Manual

6. PUBLICATION

Purpose

NCIG encourages the publication of material in the NCIG Collection and of reports and articles describing research involving the NCIG Collection, subject to the conditions specified in this policy.

NCIG recognises that the publication of some documents, records and data in the NCIG Collection may increase their potential value to Indigenous communities, researchers and other interested parties.

Appropriate publication of material in the NCIG Collection and of reports and articles describing work

carried out by the Centre is a necessary part of fulfilling the Centre's functions under the Statute.

NCIG respects the sensitive nature of material in the Collection and ensures publication in a way that protects the privacy and confidentiality of research participants and other people identified in NCIG Collection material.

Overview

This policy specifies requirements for publication of material using the NCIG Collection.

Scope

This policy applies to:

1. NCIG Board and committee members, staff, collaborators in NCIG Research, and to external parties who work collaboratively with NCIG in activities that lead to publication of data, findings, reports, articles, or other forms of publication.
2. Investigators, collaborators and authors of articles that report the results of External Research Projects.

Policy statement

1. NCIG distinguishes between material in the Collection that relates to the Centre (its history, operations, processes, etc.) and material that relates to research participants, their families and communities (records about specific people, data obtained from specific people, etc).
2. Material relating to the Centre is published in line with the usual requirements for academic publishing.
3. Publication of material relating to research participants is directed by their and their community's wishes.
4. NCIG does not publish private or confidential documents in its Collection unless free, prior and informed consent for publication has been obtained from appropriate parties.
5. NCIG does not publish identifying information about research participants unless free, prior and informed consent for publication has been obtained from appropriate parties.
6. NCIG publishes non-private, non-confidential documents and records in its Collection under a Creative Commons Attribution-ShareAlike International Licence.
7. Research findings that relate to a community must be discussed with the community. A manuscript describing findings that relate to a community must incorporate feedback from community

discussions. The NCIG Board must be satisfied that the community's response has been properly addressed before a manuscript can be published.

8. Researchers outside NCIG who contribute to NCIG Research are included as authors of manuscripts reporting research findings.
9. NCIG makes published data, records, reports and articles available to participants and their communities. The Centre also provides accounts of published work in formats that enable community members to gain an adequate understanding of the work.
10. Articles reporting the results of External Research projects must include NCIG as a corporate or group author in line with the Recommendations of the International Committee of Medical Journal Editors to facilitate communication and feedback to participants and communities.
11. NCIG's corporate authorship does not imply inclusion of individual members of NCIG as authors, collaborators or investigators in an article, unless their individual contribution to the work reported in the article justifies inclusion.

7. CONFLICT OF INTEREST

Purpose

NCIG Personnel are required to act in the interest of NCIG and in the interests of participants and Indigenous communities. They may have interests and/or commitments that conflict with their commitment to NCIG.

The ANU Policy on Conflict of Interest and Commitment applies to NCIG Personnel who are ANU Staff Members.

S.17 of the Statute (Duty of members to disclose interests) applies to NCIG Personnel who are Board members.

A specific NCIG policy on conflict of interest and commitment is necessary, however, because some NCIG personnel, for example, persons appointed by the Board to sit on advisory committees, are neither ANU Staff Members nor Board members.

This policy largely follows the ANU policy on conflict of interest and commitment. Conflicts of interest are reported to the Chair of the NCIG Board for noting and to consider what, if any, mitigating action is required.

Overview

This policy defines conflict of interest as it may exist for NCIG Board members, staff and committee members and specifies how conflicts of interest are managed to support ethical and transparent management and use of the Collection.

Scope

This policy applies to NCIG Personnel.

Policy statement

1. Interests and commitments that may constitute a conflict of interest include:
 - Financial interests that may be affected by the outcome of NCIG operations or that may impact the interest of participants or Indigenous communities or with their decision to consent to participate in NCIG
 - Family interests that may be affected by the outcome of NCIG operations or that may impact the interest of participants or Indigenous communities or with their decision to consent to participate in NCIG
 - Professional interests separate from NCIG operations that may be affected by the outcome of NCIG operations including research projects and programs, research collaborations, and disputes; or that may impact the interests of participants or Indigenous communities or with their decision to consent to participate in NCIG.
2. NCIG Personnel must declare to the Convenor any interest or commitment they have that potentially or actually conflicts with their commitment to NCIG, or with the interests of NCIG, participants or Indigenous communities, or that might be perceived to conflict with their commitment to NCIG or with the interests of NCIG, participants or Indigenous communities. The Director of the Centre must declare any such conflicts to the Board Chair.
3. The Convenor or Board Chair determines what, if any, course of action is taken to resolve a declared conflict of interest or commitment.
4. NCIG Personnel may apply to access and use material in the NCIG Collection for research purposes, but in doing so they automatically have a conflict of interest. As a result, they cannot participate in or influence decisions about their application.
5. NCIG Personnel must not use their privileged information about NCIG operations or material in the NCIG Collection to further their own separate interests and commitments. They cannot, for

instance, use privileged information to:

- conduct research on controlled material in the NCIG Collection without an Access Agreement
 - apply for funding for research or any other purpose, or gain any other form of professional advantage that is not part of their commitment to NCIG, for which an Access Agreement does not exist
 - prevent or hinder the legitimate pursuit of research or other legitimate activities by people outside NCIG.
6. NCIG Personnel cannot knowingly act in any other way that is inconsistent with their commitment to NCIG or to the interest of NCIG, participants or Indigenous communities.
 7. NCIG Personnel must consult the Convenor or the Board Chair, if they are unsure about their use of privileged information or if they are unsure whether their other interests and commitments conflict with their commitment to NCIG or with the interest of NCIG, participants or Indigenous communities.
 8. Declared conflicts of interest are reported to the NCIG Board at the next meeting for noting.

Related material

- ANU Policy: Conflict of interest and commitment
- NCIG Board Handbook

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.

ANU means The Australian National University.

ANU Staff Member means a person who is employed by the University, or who is given Academic Status or who has official visiting status.

the Centre means National Centre for Indigenous Genomics.

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.

Convenor means the chairperson of a committee formed by the Board, or the NCIG Director, or the Chair of 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.

Informed consent means consent should be a voluntary choice, and should be based on sufficient information and adequate understanding of both the proposed research and the implications of participation in it. National Statement on Ethical Conduct in Human Research (2007) (Updated May 2015)

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 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.

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, artefacts 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.