Procedure: Collection, storage and disposal of human biospecimens in research

Purpose

This procedure describes the requirements for University staff, students, emeriti and visitors seeking ethical approval to use Human Biospecimens in research projects.

Definitions

Community: A collection of individuals, which may extend from the whole population to a smaller grouping associated by cultural, ethnic, geographical, social or political factors or some other commonality.

Confidentiality: The obligation of people not to use private information (whether private because of its content or the context of its communication) for any purpose other than that for which it was given to them without the consent of the individuals from whom the information was collected.

Consent: A person's or group's agreement, based on adequate knowledge and understanding of relevant material, to participate in research.

Custodian: The researcher responsible for the management of a Human Biospecimen. The Custodian works with other key stakeholders in the management of the resource, including the tracking of all relevant documentation for the resource, and is responsible for ensuring that policies on access to the resource are in place and are implemented according to appropriate guidelines.

Data: As defined by the National Statement, data refers to bits of information in their raw form. Data refers to not only the original, raw data, but also to cleaned data, transformed data, summary data, data derived from analysis, and metadata (data about data). It can also refer to research outputs and outcomes. (See Chapter 3.1, Element 4). Note: Information generally refers to data that have been interpreted, analysed or contextualized.

Databank: A systematic collection of data

Ethics Review: Review of proposed research by an institutional Human Research Ethics Committee registered with the NHMRC, a delegated committee of the HREC, or an equivalent ethical review body (e.g., an international Institutional Review Board).

Human biospecimen: The term as defined in the National Statement, refers to any biological material obtained from a person including tissue, blood, urine, sputum and any derivative from these including cell lines. It does not include non-human biological material such as micro-organisms that live on or in a person unless such non-human biological material is contained within a Human Biospecimen.

Material Transfer Agreement: Is a legal agreement between two parties that is used to define the terms and conditions under which materials may be transferred from one party to the other and signed by an authorized delegate of those parties.

Participant Information Sheet: communicates the purpose, methods, demands, risks and potential benefits of the research.

Privacy: a domain within which individuals and groups are entitled to be free from scrutiny of others.

Overview

1. This procedure covers:

a. what information needs to be recorded about the source, nature and reason for collection of the Human Biospecimens;

b. requirements about participant consent including circumstances where waiver of consent may be justified;

c. confidentiality of samples and information;

d. access to samples and information;

e. disposal of samples; and

f. socio-cultural considerations bearing on these issues.

These are in addition to any additional considerations covered the approved Ethics Review. In the event of conflict this Procedure shall take precedent.

Procedure

2. This procedure is consistent with the National Statement on Ethical Conduct in Human Research (the 'National Statement') and the Australian Code for the Responsible Conduct of Research, 2018 (the 'Code'). Researchers must demonstrate that human biospecimens will be collected, stored, used and disposed of in accordance with:

* the Policy: Collection, Storage and Disposal of Human Biospecimens in research;

- this procedure;
- all relevant legislation and regulations;
- National Statement; and
- Ethics Review Approvals.

3. Researchers in any doubt should consult the Research and Innovation Services for guidance.

Information on the source, nature, and reason for collection of the human biospecimens

4. Where a proposed research project, carried out at the University, or primarily by University staff, involves any use of Human Biospecimens, it must be reviewed and approved by the HREC before the research can commence. This includes instances where Human Biospecimens are taken for:
    - normal diagnostic or therapeutic purposes and are then used for research or teaching purposes; or
    - samples obtained solely for the purpose of research or teaching.
5. Use of human biospecimens by University staff also requires approval by the ACT Health Human Research Ethics Committee if the staff members are also employed by ACT Health, and/or when participants are recruited through and Human Biospecimens collected at any ACT Health clinical sites (e.g. The Canberra Hospital). Under the Memorandum of Understanding between the ACT Health HREC and the ANU HREC, in such cases the ACT Health HREC is regarded as the primary HREC and the ANU HREC as the secondary HREC, with ANU HREC review expedited under the provisions of Chapter 5.3 of the National Statement regarding avoidance of duplication of ethical review. For information regarding interstate approvals, refer to the ANU Ethics website.
6. Human Biospecimens collected at sites other than ACT Health require full approval from the ANU HREC or expedited approval if approved by another authorised Australian HREC.
7. Human Biospecimens collected overseas may be subject to additional regulations and requirements which the researcher/Custodian is responsible for securing in addition to ANU HREC approval.
8. In terms of human biospecimen collection, the *Transplantation and Anatomy Act 1978* (ACT) (and other state-specific Human Tissue Acts) legislates for donation of

Human Biospecimens by living persons, effects of consents and authorities, revocation of consent or agreement, donations of Human Biospecimens after death, donations for anatomical purposes, and regulation for schools of anatomy. It provides a framework for the consensual donation of blood, tissue and organs for transplantation, and for scientific, therapeutic or medical purposes. Custodians are responsible for compliance with Human Tissue Acts.

9. The use of cadaveric Human Biospecimens for research is governed by the National Statement. Any wish expressed by a person about the use of their biospecimens post-mortem should be respected. If no such wish is discovered, researchers seeking to collect Human Biospecimens post-mortem should obtain consent from the person(s) authorised by any relevant legislation.

Information and consent

10. Participants must receive clear information about whether their biospecimen samples will be identified, and if so, how. If the research is likely to produce information relevant to the health and wellbeing of the person from whom the biospecimens were derived, their relatives, or their community, the consent strategy should clarify whether the participants (or their relatives, or community) will have the choice to be provided with these findings and how this will be managed. An ethically defensible plan to allow such disclosures should be included in the research proposal submitted for Ethical Review.
11. Procedures to allow participants to be identified for appropriate follow-up should, wherever possible, be included in the research proposal. Proposals for Ethics Review should include a statement about these procedures, including details of additional diagnostic procedures and the process for reporting information to relevant health professionals, particularly clinicians and pathologists.
12. Consent processes and documentation are subject to the approval of the HREC and must comply with relevant regulations. Consent for the use of Human Biospecimens may be specific, extended or unspecified, written or, in exceptional circumstances, oral. Extended or unspecified consent may need to include permission to enter the original data or tissue into a databank or tissuebank. Consent waivers may be granted by the HREC after consideration of the general conditions set out by the National Statement and/or relevant exceptional circumstances.
13. The use of Human Biospecimens for any purpose other than specified in the approved Ethics Review constitutes a variation, and requires further Ethics Review.

Changes to protocols without approval are a breach of the Code and may be considered research misconduct as per the University's Research misconduct and serious research misconduct procedure.

14. Treatment of Human Biospecimens within research must be consistent with conditions stated in the Information Sheet approved under the Ethics Review and in line with the Ethics Review itself, including: the type of biospecimen, collection, amount, frequency, authorised personnel for access, management and analysis, duration and security of storage, conditions for re-use, withdrawal of consent or removal of samples/data from research or archiving.

Confidentiality

15. The *Privacy Act 1988* (C'th) specifies obligations and responsibilities in relation to privacy, especially as it relates to the collection, use, storage and dissemination of personal information. Researchers and Custodians of a databank must observe any confidentiality agreement with the participant about stored data, and Custodians must take every precaution to prevent the data becoming available for uses to which participants did not consent. It is the duty of the Custodian to ensure that the data are used responsibly and respectfully, and that the privacy of participants is safeguarded. Researchers must ensure the confidentiality and privacy of stored genetic information or research results relating to identified or re-identifiable participants. Such information or research results must be disclosed to treating clinicians only in accordance with the consent given for the research.
16. Human Biospecimens for research and associated confidential data must be securely stored and only accessible to authorised researchers and any others for whom explicit participant consent for access has been agreed, as approved under the Ethics Review.
17. The NHMRC *Guidelines under Section 95A of the Privacy Act 1988* (2014) provide a framework for the use and disclosure of health information for the purpose of research or compilation or analysis of statistics, relevant to public health or public safety. The research activity in which the health information is to be collected, used or disclosed must be approved under the Ethics Review.

Privacy of samples and information

18. Subject to Ethics Review consent data may be collected, stored or disclosed in three mutually exclusive forms:

- individually identifiable data, where the identity of a specific individual can reasonably be ascertained. Examples of identifiers include the individual's name, image, date of birth or address;
- re-identifiable data, from which identifiers have been removed and replaced by a code, but it remains possible to re-identify a specific individual by, for example, using the code or linking different data sets;
- non-identifiable data, which have never been labelled with individual identifiers or from which identifiers have been permanently removed, and by means of which no specific individual can be identified. A subset of non-identifiable data is that which can be linked with other data so it can be known that they are about the same data subject, although the person's identity remains unknown.

19. With advances in genetic knowledge and data linkage, and the proliferation of Human Biospecimen banks of identified material, Human Biospecimen samples should always be regarded as, in principle, re-identifiable.

Access to samples and information

20. When a research plan involves sharing data or information with other researchers, or establishing a databank, data management plan must be developed, in accordance to the National Statement and must be subject to Ethics Review.
21. In most situations, the Custodian of data will be the individual researcher or agency that collected the information, or an intermediary such as a data warehouse that manages data coming from a number of sources. In some cases, an independent Custodian may be necessary. For example, when coded data are stored in a databank, a Custodian independent of both the data collectors and the researchers may be appointed, to maintain the data in coded form while enabling individual participants to access their own identified results or data.
22. Researchers' use of data from databanks must comply with conditions specified by the providers/Custodians of the data, including, in particular, any conditions on the identifiability of the data. Where research involves linkage of datasets, approval may be given to the use of identifiable data to ensure that the linkage is accurate, even if consent has not been given for the use of identifiable data in research. Once linkage has been completed, identifiers should be removed from the data to be used in the research unless consent has been given for its identifiable use. It is the duty of the custodian to ensure that the data are used responsibly and respectfully, and that the privacy of participants is safeguarded in line with this Procedure, its related Policy and any Ethics Review.

23. Whenever research using re-identifiable data reveals information that bears on the wellbeing of participants, researchers have an obligation to consider how to make that information available to the participants. Where individual notification is warranted as agreed in the approved Ethics Review, the custodian of the data will need to take all reasonable steps to re-identify those data for that purpose.
24. Some uses of data in a databank may be detrimental to people to whom the data relate. Researchers and/or Custodians should consider denying or restricting access to some or all of the data for those uses.
25. The rarity of some genetic disorders might allow certain families or individuals to be identified by other researchers and in some cases by members of the community, even if information is given to others in non-identifiable form. For this reason, where genetic data are stored, confidentiality will usually require restrictions on the release of data for research use, which again must be in line with an approved Ethics Review.

Disposal of biospecimens samples

26. Human Biospecimens should be disposed of within the timeframe specified in the Patient Information Sheet according to standard laboratory practices.
27. Due consideration must be given to possible socio-cultural consequences of research using Human Biospecimens, including appropriate means of disposal. Issues of religious and cultural sensitivity to the collection, storage and use of particular Human Biospecimen samples should be considered. Human Biospecimens should be disposed in a manner that does not risk the participant's confidentiality. Human Biospecimens may belong to a group who are more readily identifiable and may subsequently be at some risk of discriminatory treatment.
28. Disposal of biospecimens and cadaveric remains must be done in accordance with the *Transplantation and Anatomy Act 1978* (ACT) and any health and safety requirements, and any other regulatory requirements depending on the source of the Human Biospecimens. Guidelines for handling and disposing of organs and body parts relative to autopsy are well defined in the AHMAC *National Code of Ethical Autopsy Practice (2002).*

Other considerations

Imported Human Biospecimens

29. Where Human Biospecimens are imported from another country for use in Australia, researchers must seek to establish whether there are ethical and professional

policies in that country, or the relevant institution, governing the collection of Human Biospecimens for use in research. All relevant consents from another country must be obtained, followed by Ethics Review by an approved Australian HREC.

* Where such a policy/regulation exists, and the Researcher demonstrates compliance, the HREC may consider waiving any additional consent for the use of these Human Biospecimens

30. Where it cannot be established that a policy/regulation exists, or where it exists but enquiry reveals reason to believe the Human Biospecimens were not collected in accordance with it, the Human Biospecimens should not be used for research in Australia. Any such use may be considered research misconduct as per the University's Research Misconduct and Serious Research Misconduct Procedure.

* For research with Human Biospecimens that were in collections either imported or existing overseas before the release of the National Statement, the HREC may consider waiving consent requirement.

Application to use Human Biospecimens stored in biospecimen banks

31. Specific issues to consider when applying for Ethics Review approval include:

* the original reason for which the Human Biospecimens are collected; that is, whether they were donated for the purpose of research or removed as part of a medical procedure performed for a therapeutic purpose;

* whether the proposed use and consent of the samples is different from the original purpose of collection of the stored Human Biospecimen samples;

* the research use of the Human Biospecimens, and whether it is epidemiological, non-identifying, or identifying, given that the results may have consequences for the donor or the donor's family;

* whether information of clinical importance to the health of the donor or the donor's family may be discovered and if so how that information may be communicated with particular regard to confidentiality requirements.

* whether there are commercial applications for the research outcomes and whether the donor, or an authorised third party, has been informed of those applications and any relevant potential conflicts of interest and understands and approves of such further use.

* whether the donor has been informed of his or her capacity to have the sample and associated data removed from the research project.

Human Biospecimens from external biospecimen banks and Material Transfer Agreements

32. Where Human Biospecimens to be used in a University research project are obtained from an external Human Biobank and are transferred to the control of University, the transfer of Human Biospecimens is subject to a Materials Transfer Agreement (MTA). The MTA must document the formal transfer of authority from the external institution to the University with respect to management of the Human Biospecimens.
33. Research involving human embryos and gametes, including the derivation of human embryonic stem cell lines, is separately governed by the Research involving Human Embryos and the NHMRC *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research* (2017) (ART guidelines). Research involving the derivation of embryonic stem cell lines or other products from a human embryo must be considered by the HREC as part of a licence application to the Embryo Research Licensing Committee (see Part C of the ART guidelines). The legislation and ART guidelines do not regulate the use of these products after they have been derived.
34. Once Human Biospecimens have been derived from human embryos, gametes or foetuses, the requirements of this Procedure apply for any subsequent use in research.

Ethical considerations specific to participants

35. Section 4 of the National Statement refers to ethical considerations that apply to certain categories of research participants. These include:

* the woman who is pregnant and the fetus *in utero* (as per the above section),
* children and young people,
* people in dependent or unequal relationships,
* people highly dependent on medical care who may be unable to give consent,
* people with a cognitive impairment, an intellectual disability, or a mental illness,
* people who may be involved in illegal activities, and
* Aboriginal and Torres Strait Islander Peoples.

Researchers collecting, storing or using Human Biospecimens or associated data from participants in the above categories, must become familiar with the specific ethical considerations outlined in the National Statement when preparing their submissions for Ethical Review.

Research with First Nations Peoples

36. As outlined in *ANUP_007402 Responsible Conduct of Research Policy*, and in accordance to the National Statement, researchers must appropriately and respectfully engage with First Nations Peoples before conducting any work that involves collection, use or storage of Human Biospecimens in their communities. *The AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research (2020)* and the *NHMRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)* should be consulted for guidance when seeking Ethical Review.

37. The Ethical Review process for approval of this research must include assessment by or advice from:

* people who have networks with First Nations Peoples and/or knowledge of research with First Nations Peoples; and
* people familiar with the culture and practices of First Nations People with whom participation in the research will be discussed.

At the ANU, the Indigenous Research Advisory Group will work closely with the HREC to assess these applications.

Old biospecimens

38. The question sometimes arises concerning the need for application of this policy to Human Biospecimens of some antiquity. If Human Biospecimens are identified by a person or a community as being culturally or biologically connected to them, then the Human Biospecimens policy and this Procedure should be followed insofar as it is practical and reasonable to do so and in line with Ethical Review.

Human research Ethics Review at the University

39. All information relative to human research ethical review at the University, including contact details, can be found at: https://services.anu.edu.au/-support/ethics-integrity.

Document information

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