

# Policy: Collection, storage and disposal of human biospecimens in research

## Purpose

The policy outlines the obligations and responsibilities of the University for the ethical use of Human Biospecimen samples in research studies.

## Scope

The policy and associated procedure apply to:

- ANU academic & professional staff, honorary staff, visitors, emeriti and students collecting human biospecimens or undertaking research involving the use of humans biospecimens.
- Members of the ANU Human Research Ethics Committee (ANU HREC) reviewing protocols involving Human Biospecimen samples and potential research participants/donors.

## Overview

### **Additional documents included by reference here in this Policy**

The National Statement on Ethical Conduct in Human Research (2007– Updated 2018) (“the National Statement”) recommends that institutions develop a policy for the collection, storage and disposal of Human Biospecimens in Research. It provides guidance on:

- requirements for consent (Chapters 2.2 – 2.3);
- use of human biospecimens in laboratory-based research, including biobanking and use of biospecimens collected for clinical purposes (Chapter 3.2);
- genomic research (Chapter 3.3);
- collecting human biospecimens from particular categories of participants (Chapters 4.1 to 4.8), and
- institutional responsibilities and the ethics review process (Chapters 5.1 – 5.7)

Policy principles and associated operational procedures are described more fully in the following documents:

- [Privacy Act 1988 \(Cth\)](#)

- Transplantation and Anatomy Act 1978 (ACT)
- National Health and Medical Research Council (NHMRC) Guidelines under Section 95 of the Privacy Act 1988 (2014) and NHMRC Guidelines approved under section 95A of the Privacy Act (2014), which provide a framework for appropriate collection, use, protection or disclosure of personal information.
- National Code of Ethical Autopsy Practice
- ACT Health Ethics Committee Guidelines for Submission
- The Australian Code for the Responsible Conduct of Research (2018)
- ANU Human Research Ethics Committee Terms of Reference

## Definitions

**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.

**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.

## Policy statement

1. The University must ensure that any research it conducts or is responsible for, involving the collection, storage, and disposal of Human Biospecimens:
  - observes the basic ethical principle of respect for the donor, including the provision of full information on the research and informed donor consent (where possible),

professional removal of samples and secure storage of samples and associated data to maintain confidentiality and privacy;

- considers the psychological, social and cultural or religious sensitivities of the donor when soliciting or accepting Human Biospecimens;
- is designed and conducted in accordance with the Australian Code for the Responsible Conduct of Research, 2018 (the Code);
- has an approved Ethics Review and is monitored in line with the approved protocol and in accordance with the National Statement;
- addresses the need, where the research finds information of importance to the health of the donor(s) and/or donor's blood relatives or their Community, for an ethically defensible plan to manage the disclosure or non-disclosure of this information as approved by an Ethics Review;
- is carried out safely, in accordance with the University's Work Health and Safety principles;
- has an approved Ethics Review where the acquisition of Human Biospecimens from an external source for research at the University and/or the supply of Human Biospecimens to an external source is involved; and
- is subject to a Materials Transfer Agreement where Human Biospecimens between the University and an external tissue bank transfer (or vice versa) is involved.

2. In accordance with the National Statement, Human Ethics Review Committee members are responsible for:

- deciding whether, in their judgement, a proposal submitted for review which involves the use of Human Biospecimens meets the requirements of the National Statement and is ethically acceptable;
- disclosing any actual or potential conflict of interest that bears on any research coming before the Committee for review.

3. In accordance with the National Statement, Custodians are responsible and accountable for:

- submitting a proposal for Ethical Review which demonstrates that the research involving the use of Human Biospecimens has merit and reflects the ethical values of justice, beneficence and respect for humans;
- acquiring all necessary ethical approvals to use Human Biospecimens in their research prior to commencement of research/analysis/storage;

- demonstrating that the Human Biospecimens are collected, stored, used and disposed of in accordance with this policy, procedure and any Ethics Review approval;
- monitoring, and prompt reporting of any adverse events or unexpected outcomes in line with the Ethics Review and this Policy;
- retaining detailed records relating to Human Biospecimen samples in line with the approved Ethics Review; and
- disclosing any actual and potential conflicts of interest that bear on the proposed research, both during the review process, during the research and when communicating the results of the research.

### **Human research ethics review at ANU**

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

## Document information

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