

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

Purpose

The policy outlines the obligations and responsibilities of the University and its staff, Students, Emeriti and Visitors for the ethical use of human biospecimen samples in research studies.

Overview

The *National Statement on Ethical Conduct in Human Research* (2007) recommends that institutions develop a policy for the collection, storage and disposal of human biospecimens in Research. The policy principles and associated operational procedure are described more fully in the following documents:

- [National Statement on Ethical Conduct in Human Research](#) (“the National Statement”) which provides guidance on: Databanks including human biospecimen ‘banking’ (Chapter 3.2); The use of human biospecimens for therapeutic purposes (Chapter 3.3); The use of human biospecimens for laboratory-based research (Chapter 3.4); human genetics (Chapter 3.5); Collecting human biospecimens from particular categories of participants (Chapters 4.1 to 4.8)
- [National Code of Ethical Autopsy Practice](#)
- [Transplantation and Anatomy Act 1978](#)
- [ACT Health Ethics Committee Guidelines for Submission](#)
- [University Policy: Conflict of Interest](#)
- [Privacy Act \(1988\)](#)
- [Australian Code for the Responsible Conduct of Research](#)

Scope

The policy and associated procedure applies to:

- ANU staff, visitors, emeriti and students undertaking research involving the use of biospecimen samples;

- Members of the ANU Human Research Ethics Committee reviewing protocols involving human biospecimen samples; and
- Potential research participants.

Definitions

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, howsoever sourced. It does not include non-human biological material such as micro-organisms that live on or in a person.

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.

Policy statement

1. The University is committed to ensure that any human research it conducts or is responsible for, involving the collection, storage, and disposal of human biospecimen samples:

- 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 these to maintain confidentiality and privacy;
- considers the psychological, social and cultural or religious sensitivities of the donor when soliciting or accepting human biospecimens;
- must be designed and conducted in accordance with the National Statement and pre-approved by the relevant University Human Research Ethics Committee;
- must be ethically reviewed and monitored in accordance with the University Human Research Ethics Committee requirements;
- 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 approved by the University Human Research Ethics Committee;
- which involves 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 approved by the University Human Research Ethics Committee; and

- which transfers human biospecimens between the University and an external tissue bank or vice versa is subject to a Materials Transfer Agreement.

2. In accordance with the National Statement, researchers are responsible and accountable for:

- acquiring all necessary ethical approvals to use human biospecimen samples in their Research project prior to commencement of Research;
- demonstrating that the human biospecimens are collected, stored, used and disposed of in accordance with this policy, procedure and University Human Research Ethics Committee approval; and
- monitoring, and for prompt reporting of any adverse events or unexpected outcomes, and for retaining detailed records relating to human biospecimen samples.

Human research ethics review at ANU

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