Human Biospecimen Use for Research and Teaching Policy

Section 1 - Purpose

(1) This Policy states the University's requirements for human biospecimen use for research and teaching activities.

(2) This Policy is not intended to apply to the use of cadavers, nor the use of samples from cadavers.

(3) Before cadavers are considered for use in research or teaching, contact Research Services – Research, Ethics Integrity & eResearch.

(4) This Policy is restricted to the use of human biospecimens for research, or teaching in which there is no diagnostic component with respect to the donor.

(5) This policy does not cover the use of human biospecimens for any medically related diagnostic research.

Section 2 - Scope

(6) This Policy applies to:

a. anybody undertaking, supervising or supporting research or teaching activities at, or under the auspices of, the University, and
b. members of the University's Human Research Ethics Committee (HREC) reviewing responsibilities and obligations concerning human tissue samples and approvals.

Section 3 - Principles

(7) This policy is aligned with the National Statement on Ethical Conduct in Human Research (the National Statement) and is a supplementary policy which does not replace any other requirements under the National Statement. It is designed to ensure that human biospecimens are collected, used, stored and disposed of in accordance with University policy, procedures and HREC approvals and in a manner that meets the requirements under the National Statement.

(8) It also sets out the requirements for research or teaching activities that include the use of human biospecimens within the University prior to the commencement of such activities.

(9) A staff member must be nominated as accountable for monitoring and reporting in a timely manner any unexpected or adverse outcomes related to human biospecimens research and teaching activities, and for maintaining detailed records.

(10) This policy is to be used in conjunction with the approvals procedures of the HREC.

(11) This policy ensures the University:

a. adheres to ethical requirements to the donor, including obtaining informed consent (where this can be obtained), providing complete information on the research or teaching, including research outcomes, professional standards for sample removal, secure storage, confidentiality and privacy requirements;
b. considers the social, cultural, religious and psychological sensitivities of the donor when sourcing or accepting human biospecimens for research or teaching activities;
c. reviews and monitors the policy to meet ethical requirements in accordance with the requirements of the HREC and considers the importance of the health of the donor(s), their relatives and the community related to research or teaching activities, including, but not limited to, ethical requirements to manage the disclosure or non-disclosure of information related to approvals by the HREC;
d. considers the approval requirements of the HREC for the acquisition of and/or supply of human biospecimens related to an external source for research or teaching activities;
e. ensures a transfer agreement is in place for research or teaching activities that involve human biospecimens transfers, such as, the transfer of human biospecimens between the University and an external source.

Special considerations for human embryos, gametes and fetal tissue

(12) Research involving human embryos and gametes, including the derivation of human embryonic stem cell lines, is separately governed by the Research Involving Human Embryos Act 2002 and the Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (ART Guidelines), issued by the National Health and Medical Research Council (NHMRC). Research involving the derivation of embryonic stem cell lines or other products from a human embryo must be considered by a 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. Once human biospecimens have been derived from human embryos, gametes or fetuses, the requirements of the National Statement apply for any subsequent use in research.

(13) Specific requirements for research involving fetal tissue are detailed in Chapter 4.1 of the National Statement, 'Women who are pregnant and the human fetus'.

Project description

(14) Where a proposed research or teaching project is to be conducted at the University and/or involving University staff utilising human biospecimens, as a comprehensive project description and application must be submitted to the HREC and approval received before the research or teaching can commence.

(15) The project description must outline the source of human biospecimen samples.

(16) If samples are to be sourced from an external party, the arrangements and written agreements involved in provision of samples and any regulations enforced by the external party on use of the samples must be detailed within the application. If needed, legal authorisation from the University should be sought in advance of ethics approval.

(17) If University staff are to be involved in sample collection their actions must be in accordance with the ACT's Transplantation and Anatomy Act 1978 which legislates for donation of biospecimens (tissue) by living persons, effects of consents and authorities, revocation of consent or agreement, donations of tissue after death, donations for anatomical purposes and regulations for schools of anatomy.

(18) The project description must outline method(s) of transport of the samples to and from the University.

(19) The project description must outline the method and location of storage for the human biospecimen samples, including management of access to samples in storage. Appropriate record-keeping must be in place and access must be restricted to research or teaching personnel directly involved in the project.

(20) The project description must outline the method of disposal of human biospecimen samples, long-term storage of

samples or components of samples or return of samples to their external source on completion of research or teaching project.

(21) The project description must outline the management of confidentiality and privacy issues concerning samples. Sample identification methods must be comprehensively outlined whether donor identity is known or unknown.

(22) The project description must contain a detailed protocol for use of human biospecimen samples during the research project or teaching activity and information on the appropriate dissemination of results (as appropriate) arising from use of these samples. Donor confidentiality must be specifically addressed.

Information and consent

(23) Requirements concerning participant and or donor consent must be in alignment with the National Statement, Chapter 2.2, 'General requirements for consent' and Chapter 2.3, 'Qualifying or waiving conditions of consent'.

Commercialisation

(24) There should be no trade in human biospecimens for research purposes.

Collection, retention and use

(25) Anybody undertaking research or teaching activities under the auspices of the University of Canberra must meet relevant legislative requirements that relate to the collection, retention, use and disposal of human biospecimens.

Section 4 - Definitions

TERMS	DEFINITIONS
Externally Funded Research Activities	Externally Funded Research Activity is usually initiated by a research application through a competitive process, or may be a jointly initiated collaborative project between the University and an external agency (industry, government, commercial organisation, and so on), or may follow from a specific request from an external agency for a research project to be undertaken. These activities also include consultancies where research is a component of the activities provided.
Human Biospecimens	Chapter 3.2 of the National Statement on Ethical Conduct in Human Research state that human biospecimen is a broad term that, for the purposes of the Chapter, refers to any biological sample obtained from a person including tissue, blood, urine and sputum; it also includes any derivative of these, such as cell lines. It does not include non-human biological samples such as micro-organisms that live on or in a person. Research or teaching involving human biospecimens often involves special ethical consideration because of: • the way that human biospecimens are obtained; • the information that may be derived from human biospecimens and the implications of that information for the individual donor, their relatives and their community; • the significance that may be attached to the human biospecimens by individual donors and/or communities[1]. [1] * Chapter 3.2 should be read in conjunction with Chapter 3.1 and other parts of the National Statement on Ethical Conduct in Human Research.
National Statement on Ethical Conduct in Human Research (National Statement)	The National Statement sets out national standards for the ethical design, review and conduct of human research. The National Statement provides guidance on a range of important matters including: Databanks including human biospecimen 'banking'; the use of human biospecimens for therapeutic purposes; the use of human biospecimens for laboratory-based research; human genetics and collecting human biospecimens from particular categories of participants.

TERMS	DEFINITIONS
National Health and Medical Research Council (NHMRC)	An Australian Government expert funding body in health and medical research. The NHMRC is an independent statutory agency within the portfolio of the Australian Government Minister for Health and Ageing, operating under the National Health and Medical Research Council Act 1992.
Research	The concept of research is broad and includes the creation of new knowledge and/or the use of existing knowledge in a new and creative way so as to generate new concepts, methodologies, inventions and understandings. This could include synthesis and analysis of previous research to the extent that it is new and creative.
Transfer Agreement	A legal agreement between two parties that defines the terms and conditions to which samples may be transferred from one party to the other party

Status and Details

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