Chapter 3.4: Human biospecimens in laboratory based research

Introduction

‘Human biospecimens’ is a broad term that, for the purposes of this chapter, 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 microorganisms that live on or in a person.

Research involving human biospecimens often involves special ethical considerations 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 blood relatives and their community; and
- the significance that may be attached to the human biospecimens by individual donors and/or communities.

This chapter provides guidance to researchers, institutions and HRECs on the matters that require ethical consideration.

Specific considerations for human embryos, gametes and fetal tissue

Specific requirements for research involving fetal tissue are detailed in Chapter 4.1: Women who are pregnant and the human fetus.

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 (Cth) and the Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (2007) (ART guidelines), issued by the NHMRC. Research involving the derivation of embryonic stem cell lines or other products from a human embryo must be considered by a Human Research Ethics Committee (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 this Chapter apply for any subsequent use in research.

Sources of human biospecimens

Sources of human biospecimens include voluntary donation, material taken for clinical purposes, and material collected post-mortem (after death).

Human biospecimens are commonly collected, stored and distributed by researchers, biobanks, clinical pathology services, health care providers, research institutes and commercial entities, such as pharmaceutical and biotechnology companies.

Other chapters, legislation and documents that should be considered

Additional ethical guidance that may be relevant to research uses of human biospecimens is provided in this National Statement at:

- Chapter 3.2: Databanks
- Chapter 3.3: Interventions and therapies, including clinical and non-clinical trials and innovations, which provides ethical guidance on the use of human biospecimens for therapeutic purposes
- Chapter 3.5: Human genetics, which offers additional guidance on specific aspects of the use of human biospecimens for research purposes
- Chapters 4.1 - 4.8: Ethical consideration specific to participants, which offer additional guidance on ethical issues arising from collecting human biospecimens from particular categories of participants
Researchers and institutions must also meet any relevant legislative requirements that relate to the collection, retention, use and disposal of human biospecimens, including the general prohibition on trade in human tissue.

Values, principles and themes that must inform the design, ethical review and conduct of all human research are set out in Sections 1 and 2 of this National Statement and are applicable to research involving human biospecimens.

Guidelines

Prospective collection of human biospecimens for research

3.4.1 Those proposing to collect human biospecimens for research should:

- ensure that the burdens of the biospecimen collection on the donor(s) are justified by the potential benefits of the proposed research;
- ensure that those involved in the collection of the biospecimens are suitably qualified or experienced, and follow current best practice; and
- ensure that suitable provisions, including financial and governance arrangements, have been made for the intended processing, storage, distribution and/or use, and disposal of the biospecimens.

3.4.2 The consent of donor(s) should be obtained and recorded when collecting human biospecimens specifically for research in order to meet the requirements of Chapter 2.2: General requirements for consent.

3.4.3 Before potential participants consent to donation of their biospecimens, they should be given sufficient information about:

- the research for which their biospecimens are to be used and, where extended or unspecified consent is sought, sufficient information to meet the requirements of paragraphs 2.2.1 and 2.2.16;
- how their biospecimens will be stored, used and disposed of, including any processes to be adopted to respect their personal or cultural sensitivities;
- the extent to which their biospecimens will be reasonably identifiable, and how their privacy and confidentiality will be protected;
- whether or not research using their biospecimens is likely to provide information that may be important to their health or to the health of their blood relatives or their community;
- if information of the kind referred to in (d) is likely to be revealed, whether or not they will have the choice to receive this information, and how this will be managed (see paragraph 3.4.10);
- if information of the kind referred to in (d) is likely to be revealed, whether or not they will have the choice for it to be provided to their blood relatives or their community; and how this will be managed (see paragraph 3.4.10);
- whether their biospecimens and associated data may be distributed to other researchers, including those outside Australia (see paragraphs 3.4.13 – 3.4.15);
- their right to withdraw consent for the continued use of their biospecimens or associated data in research (see paragraph 2.2.6(g)), and any limitations that may be relevant to their withdrawal of consent; for example, as a consequence of the removal of identifiers, or the prior distribution and/or use of their biospecimens;
- any relevant financial or personal interests that those engaged in the collection, processing, storage and distribution and use of their biospecimens may have (see Chapter 5.4: Conflicts of interest); and
- any potential for commercial application of any outcomes of the research involving their biospecimens, how this will be managed and to whom the benefits, if any, will be distributed.

3.4.4 For human biospecimens collected for research purposes (including biobanks), there should be ethical review and approval by an HREC of the proposed consent, collection, processing, storage and distribution or disposal.

Human biospecimens obtained after death for research

3.4.5 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 obtain human biospecimens post-mortem should obtain consent from the person(s) authorised by relevant legislation.

Ethical review of research involving human biospecimens

3.4.6 Institutions, researchers and other organisations that conduct research involving the use of human biospecimens have a responsibility to ensure that the research is designed, reviewed, approved and conducted in accordance with this National Statement and other relevant guidelines and legislation.

3.4.7 The ethical review of proposed research involving the use of human biospecimens must consider the circumstances in which the biospecimens were obtained and any known limitations the donor(s) placed on their use during the consent process.

3.4.8 In determining the level of ethical review appropriate for the research involving the use of human biospecimens, the responsible institution and researcher should consider:
a. whether the research involves any risks to the donors, their blood relatives or their community that are more serious than discomfort (see Chapter 2.1: Risk and Benefit); and
b. whether the research may give rise to information that may be important for the health of the donors, their blood relatives or their community where the identity of the donors will be known to, or can reasonably be ascertained by, those conducting the research or with access to health or research data related to donors.

3.4.10 Where proposed research involving the use of human biospecimens may reveal information that may be important for the health of the donor(s), their blood relatives or their community, whether anticipated or incidental to the scope of the research, researchers should prepare an ethically defensible plan to describe the management of any proposed disclosure or non-disclosure of that information. This plan must be approved by an HREC and should include consideration of the following:

a. The circumstances in which the biospecimens were obtained, including the type of consent provided (see paragraph 2.2.14) and the manner in which the consent was obtained;

b. the likelihood of the research generating information that may be important for the health of the donor(s), their blood relatives or their community;

c. whether a recognised intervention exists that can benefit or reduce the risk of harm to the donor(s), their blood relatives or their community from any health impact revealed by this information;

d. the resource requirements and infrastructure in place to support the return of information of the kind referred to in (b) and (c) in an ethically appropriate manner;

e. whether participants will be given a choice to receive such information;

f. whether there is a pathway to identify and recontact the donor(s), their blood relatives or their community, taking into account the relationship between the researchers and the donor(s), if any;

g. the potential for sampling or coding errors that may compromise the certainty that the biospecimens came from a particular donor;

h. whether the findings of specific tests being undertaken as part of the research have been produced or validated in an accredited laboratory; and

i. who will take responsibility for any subsequent care requirements.

Use of human biospecimens collected for clinical purposes

3.4.11 Where human biospecimens were obtained for clinical purposes and have been retained by an accredited clinical pathology service, the biospecimens may be used for research purposes if:

a. the identity of the donor is not necessary for the activity (see paragraph 3.4.9); or

b. where the identity of the donor is required for the purposes of the research, a waiver of consent (see paragraph 3.4.12) has been obtained.

Waiver of consent

3.4.12 Where it is contemplated that proposed research will involve the use of human biospecimens that have been obtained without specific consent for their use in research (e.g. where biospecimens were collected for clinical investigation), or where the proposed research is not consistent with the scope of the original consent, the biospecimens may be used only if an HREC is satisfied that the conditions for waiver of consent are met (see Chapter 2.3: Qualifying or waiving conditions for consent). Particular consideration should be given to:

a. whether there is a pathway to identify and recontact the donor(s) in order to seek their informed consent to the use of their biospecimens in research; and

b. whether there is a known or likely reason for thinking that the donor(s) would not have consented if they had been asked.

Importation and exportation of human biospecimens for research

3.4.13 Where it is intended that human biospecimens will be, or where the biospecimens have been imported from another country for use in research in Australia, researchers must establish whether these human biospecimens were obtained in a manner consistent with the requirements described in this National Statement and relevant Australian legislation.

3.4.14 Where it cannot be established that the human biospecimens described in paragraph 3.4.13 were obtained in a manner consistent with the requirements described in this National Statement and relevant Australian legislation the biospecimens should not be used for research in Australia.

3.4.15 Human biospecimens obtained for research in Australia may be sent overseas for research in accordance with institutional policy, if:

a. ethical approval by an appropriate ethical review body for importation of the biospecimens is submitted; or

b. the exportation of the biospecimens is consistent with the original consent and ethical approval is provided by an HREC.

Transition provisions for existing biospecimens

3.4.16 Where biospecimens were obtained domestically or via importation prior to the effective date of this guideline (December 2013), the
biospecimens may continue to be used in Australia for approved research provided that the researcher’s institution ensures that:

a. there is sufficient evidence that the samples were obtained in a manner consistent with any prior guidelines and/or the accepted ethical practice at the time of collection; and
b. the proposed research for which the biospecimens will be used is within the scope of the consent provided by the donor(s).

Conscientious Objection

3.4.17 Those who conscientiously object to being involved in conducting research using human biospecimens derived from human embryos, gametes, fetuses or embryonic or fetal tissue should not be obligated to participate, nor should they be put at a disadvantage because of their objection.