University of Dundee

Policy for the Use of Human Tissue within Clinical and Non-clinical Research Studies

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Biorepository Remit - Oversight

The Tayside Biorepository is responsible for overseeing the governance of all local collections of human tissue intended for use in research within the University of Dundee ("internal" use) or human tissue transferred by the University of Dundee for use in research by a third party ("external" use).

It is important that both staff and students are familiar with the policy and the procedures within to ensure that standards of best practice are applied to research that involves the collection, transport, storage, and use of human tissue.

Staff Duty of Adherence to Policy - Registration of Use

Staff collecting, distributing, receiving and/or storing human tissue for internal or external use in research **must** register activity via the Tayside Biorepository tissue bank. Students should be aware of this requirement but must inform their supervisor(s) if there is a need to register human tissue within the University of Dundee.

The registration must be carried out by the University of Dundee staff member with "custodianship" of the collection, distribution, receipt, or storage of human tissue. Human tissue for use by students must be registered by the supervisor with primary responsibility for supervising the student's use of the tissue in their research (usually the first supervisor). Information recorded must include the type of tissue, the number of samples and where these samples are stored within the University of Dundee.

Categories of tissue covered by this Code include:

- Tissue that has NHS Research Ethics Committee (REC) approval including Clinical Trials of Investigational Medicinal Products (CTIMPs) and Non-CTIMPs that collect human tissue samples from NHS patients
- Non-clinical projects that require approval through School Research Ethics Committees (SRECs) that involve the collection of tissue samples from healthy volunteers
- Imported tissue from accredited tissue bioresources and collaborators.

All collections/research activity **must** have the appropriate ethical approvals in place with evidence of consent/authorisation, and where appropriate Material Transfer Agreements, prior to registration. This policy clarifies what approvals are appropriate for different categories of project.

Staff Duty to Maintain Registration and Inform the Tayside Biorepository if Leaving

It is important that registrations are monitored once a year by the registered custodian to ensure that the information is up to date and relevant. If you are due to leave NHS Tayside or the University of Dundee and you have a collection of tissue you must inform the Tayside Biorepository so that appropriate support can be provided if required for the registration of tissue or the transfer of the collection to an alternate registered custodian, future use, or destruction of tissue samples. If notification is not provided and a collection is left without support, the Tayside Biorepository shall have the right to either transfer the collection to an appropriate custodian or shall provide authorisation and support for the destruction of the collection.

1. Definitions (see Appendix A for Supplementary List of Relevant Human Tissue)

Human tissue is defined as material that has come from a human body and consists of, or includes, human cells. This can include a wide range of tissue types including skin samples, blood samples, sputum, and saliva, gametes, hair and nails from the living or deceased.

It excludes: Embryos outside the body; cells manufactured outside of the human body (e.g. established cell lines) and/or any extracted cellular components where no whole cells remain (e.g. extracted DNA and RNA are not classed as bodily material).

Relevant human tissue (Refer to appendix A) is defined as "material, other than gametes, which consists of or includes human cells".

Although outside the definition of relevant human tissue, gametes fall within the remit of the Human Fertilisation and Embryology Act 1990 and are regulated by the Human Fertilisation and Embryology Authority (HFEA).

Surplus human tissue refers to samples that are collected as part of the routine patient pathway and are no longer required for diagnosis or patient care. They would otherwise be discarded as clinical waste.

2. Best Practice

Human Tissue must be acquired, treated, stored, and disposed of with respect. Research activity involving the use of relevant human tissue within the University of Dundee must be conducted using best practice in accordance with the guidance and direction from:

- The Human Tissue Act 2004, Section 45 (only Section 45 applies in Scotland)
- The Human Tissue (Scotland) Act 2006
- NHS Research Scotland Human Tissue Accreditation Scheme Summary

Additional guidance is available via UK Research and Innovation (UKRI), specifically the Scotland summary, along with further information on using human samples in research.

This policy describes the steps that a researcher must take within the following non-exclusive categories:

- Ethical approval
- Consent/ Authorisation for the use of human tissue within research projects
- Material Transfer Agreements
- Confidentiality, Traceability & Retention of human tissue for research
- Suitability of Premises for the storage and use of human tissue in research

It is the responsibility of every member of the research group that supports the participant and is entrusted with their tissue sample to routinely follow these guidelines; this will strengthen the chain of trust between the participant and the research team.

3a. Governance Requirements/ Approvals (in detail)

Approvals required for the use of human tissue within different types of research projects at the University of Dundee depend on where tissue is held or sourced.

Before you can start a project that involves the use of human tissue samples, you must obtain the

most appropriate ethical approval. The main routes to apply for the appropriate ethics for the use of human tissue within research projects are as follows:

- If tissue can be acquired by an accredited biobank within the UK or abroad then an application can be placed with the biobank for review by a tissue access committee. Locally please contact Tayside Biorepository.
- If tissue is to be sourced through the NHS from NHS patients and is non-surplus or considered additional to routine care, then you must contact the Tayside Medical Science Centre (TASC) Research Governance Office for the appropriate Sponsor/R&D approval. This includes the requirement of tissue from patients/individuals with certain health conditions.
- For the use of tissue sourced from consented non-clinical participants excluding genetic research then an application should be submitted to the appropriate SREC. For additional information please refer to the non-clinical research ethics application procedure and procedure for best practice in research involving the use of human tissue.
- In the instance that tissue sourced from non-clinical participants is required for research that involves genetic research, advice should first be obtained from the Scientific Officer at East of Scotland Research Ethics Service.
- To obtain tissue samples from an external collaborator it is important that researchers follow the advice provided in section 5 of this policy.

3b. Application for Ethical Approval/Research Proposals

A detailed research protocol should be submitted to the relevant ethics body that includes the following information relating to the intended use of human tissue so that it can be considered for the appropriate approval:

A. Clarity of what is proposed, the question(s) the project intends to answer and methodology to include details of the type, number and format of sample(s) required.

B. A clear plan of the technical and practical aspects of the project to include the following:
    - Method of consent
    - Method of patient de-identification/Anonymization
    - Clarity on the use of the tissue samples and who is required to use the samples (e.g., include all research groups)
    - Clarity upon the storage facilities for the samples and a clear process for withdrawal of consent

C. Evidence of sufficient statistical power to the study, previous pilot data or validation of methods including previous experience of the use of human tissue within the laboratory.

D. A clear procedure for the disposal of human tissue in a respectful and dignified manner.

4. Consent/Authorisation

The overarching principle for the acquisition of human tissue samples is that of informed consent.

Researchers must provide clear, informed information to the participant to explain the type and amount of tissue required for research, what benefit this provides to the research project, what will happen to any tissue samples that are taken, what will happen to tissue samples after the experiment is finished and what personal data is required. It is important that the information provided in a participant information sheet is delivered in a clear manner and plenty of time is provided for an informed decision to be made. Potential participants must not be coerced into taking part and they must be informed of their right to withdraw their consent from the study if participants wish to do so later.

It is important that those who are required to obtain consent are appropriately trained. This can be through a Good Clinical Practice (GCP) course. TASC can provide further details on training dates for these courses.

Written consent must be obtained prior to starting a research project and a clear policy should be in place for the possibility of withdrawal of consent, the subsequent management of the tissue sample and the correction or erasure of any data held on an individual participant.

Exemptions: Samples pre-2006

Collections that existed prior to 1st September 2006 can continue to be used for research without patient consent but it is advised that the use of these samples follow wherever possible the guidance within this policy to ensure best practice. For the use of tissue collected prior to 2006, local policies should be in place to ensure that clear records are maintained to confirm the number of samples used within a research project, who is using the samples and the purpose of the research.

5a. Import & Export of Tissue

1. It is good practice to gain assurance that consent has been obtained in the source country. Imported and exported tissue should be procured, used, handled, stored, transported, and disposed of in accordance with the consent given.
2. Ensure that tissue for medical research is sourced from a country with an appropriate ethical and legal framework.
3. Ethical approval should be obtained from a REC or equivalent in the source country.
4. If you cannot ensure that ethical standards are in place, the risks of accepting the material should be assessed.
5. Where material will be imported, the need to do so should be justified and documented (e.g. in terms of accessibility, quality of service, timeliness, etc.).
6. Where material will be exported, it is good practice to inform participants during the consent process that their samples and any associated data may be transported abroad and used in accordance with their consent. When exporting data abroad you must also meet any other relevant legal requirements.
7. For both imports and exports of human tissue, documented agreements should be in place to ensure all issues relating to consent are considered and agreed with the source/recipient country.
8. You should consider how to ensure sample integrity during transit.
9. There are some legal differences to consider in Scotland, but similar standards are expected for the import and export of human tissue into/out of Scotland.

It is the responsibility of the researcher to ensure that these considerations have been

documented, however for additional support please contact the Manager of Tayside Biorepository for standards of best practice.

Documentation of each consignment of imported tissue should be retained by the researcher undertaking the import for at least 5 years after disposal of the last part of tissue contained within the consignment.

Further information can be found via the MRC Research and the Human Tissue Act 2004 Import & Export summary document.

5b. Material Transfer Agreements

A Material or a Data and Material Transfer Agreement is required when human tissue is being imported or exported from the University.

- For human tissue projects that involve the Tayside Biorepository please contact the Manager of the Tayside Biorepository for completion of an appropriate agreement. The Biorepository Manager is authorised to sign these agreements.
- For clinical studies that involve NHS patients through TASC please contact TASC legal to discuss requirements. The NHS Tayside R&D Director is responsible for signing these agreements.
- For studies that involve the import of human material for research purposes into the University of Dundee or the export (excluding projects above) please consult the Material Transfer Agreements guide.

6. Suitability of Premises & Equipment

Before tissue is collected or imported researchers must ensure that the appropriate storage facilities are available. Facilities should be secure so that access is limited to only the appropriate staff who work with the tissue samples. If samples are to be stored within freezers, temperatures should be monitored to maintain optimum temperature for preservation and should be accessed only when required.

Consideration should also be given to storage space. For example, researchers must ensure that there is a contingency plan for the storage of samples in the event of a power failure and that samples are split between two freezers to prevent the potential loss of all tissue.

Where specific equipment is used to process human tissue samples, equipment must be adequately maintained and suitable for purpose. Blood processing should be carried out in centrifuges with protective buckets.

7. Disposal of Human Material

It is important that the laboratory responsible for using and storing human material has a clear policy in place for the management of human material that requires disposal by incineration. Disposal records should also be kept. This ensures dignity for the participant but also prevents storage of material that may be unused for long periods of time.

Appendix A: Supplementary list of "relevant" human tissue

Definitions:

Bodily Material: Is any tissue or sample that consists of human cells; this includes gametes, and hair and nails from the living or deceased. It excludes: Embryos outside the body; cells manufactured outside of the human body (e.g. established cell lines) and/or any extracted cellular components where no whole cells remain (e.g. extracted DNA and RNA are not classed as bodily material).

Exceptions include tissue that has been:

1. divided or created outside the human body
2. treated, processed, or lysed through a process intended to render material acellular. This would include the freezing or thawing of cells only where that process is intended to render the material acellular.

Relevant human tissue (see table below) is defined as "material, other than gametes, which consists of or includes human cells". All research involving relevant material should be conducted in accordance with the conditions of ethical approval.

Although outside the definition of relevant human tissue, gametes fall within the remit of the Human Fertilisation and Embryology Act 1990 and are regulated by the Human Fertilisation and Embryology Authority (HFEA).

This list is not intended as exhaustive or exclusive and is intended to provide guidance in respect of a number of tissue types that may be considered relevant bodily material.

Tissue Type	**Considered relevant material by human tissue authority**
Antibodies	No
Bile	Yes
Blood	Yes
Bone Marrow	Yes
Bones/Skeletons	Yes
Brain	Yes
Breast Milk	Yes
Breath condensates and exhaled gases	No
Buffy coat layer (interface between plasma and blood cells when blood is separated)	Yes
Cell lines	No
Cells that have divided in culture	No
Cerebrospinal Fluid (CSF)	Yes

Tissue Type	**Considered relevant material by human tissue authority**
Cystic Fluid	Yes
DNA	No
Eggs (Ova)	No
Embryonic Stem cells (cells derived from an embryo)	No
Embryos (outside the body)	No
Extracted material from cells e.g. nucleic acids, cytoplasmic fractions, cell lysates, organelles, proteins, carbohydrates and lipids	No
Faeces	Yes
Fetal Tissue	Yes
Fluid from cystic lesions	Yes
Gametes	No
Hair (From deceased person)	Yes
Hair (From living person)	No
Joint aspirates	Yes
Lysed cells	No
Mucus	Yes
Nail (From deceased person)	Yes
Nail (From living person)	No
Nasal and Bronchial Lavage	Yes
Non-blood, derived stem cells (derived from the body)	Yes
Non-Fetal Products of conception (The amniotic fluid, umbilical cord, placenta, membranes)	Yes
Organs	Yes
Pericardial Fluid	Yes
Plasma (if there is a risk that small numbers of platelets or other blood cells are present)	Yes

Tissue Type	**Considered relevant material by human tissue authority**
Plasma (treated to render acellular)	No
Platelets	Yes
Pleural Fluid	Yes
Primary cell cultures (whole explant/biopsy present)	Yes
Pus	Yes
RNA	No
Saliva	Yes
Serum	No
Skin	Yes
Sperm cells (spermatozoa)	No
Sputum (or Phlegm)	Yes
Stomach Contents	Yes
Sweat	No
Teeth	Yes
Tumour tissue samples	Yes
Umbilical Cord blood stem cells	Yes
Urine	Yes

Document Information

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