Bournemouth University

Medical Sciences Department

Human Tissue Facility

SOP title:	Acquiring human tissue and cells
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Amendment log

Version:	Date	Amendment(s):
0.2	June 2019	Detail added to introduction and text. References section has been updated

Abbreviations:

SOP: Standard operating Procedure

HTA: Human Tissue Authority

CoP: Code of Practice

CI: Chief Investigator

MTA: Material Transfer Agreement

PIS: Participant Information Sheet

ID: Individual Designated

Purpose: The purpose of this SOP is to ensure all relevant material is collected or sourced in full compliance with the Human Tissue Act 2004 and local governance and ethics rules.

Scope: This SOP is intended for BU researchers or students whose activities involve collecting, storing using and disposing of human tissue or primary human cells.

1. Introduction:

The use of human tissue in clinical research is strictly regulated. The Human Tissue Act (2004) requires that all organisations acquiring, storing, using or disposing of human tissue are licensed and regulated for these activities by the HTA [(1)]. The HTA standards require that all aspects of the establishment work are governed by documented policies and procedures as part of the overall governance process (GQ1).

The HTA licenses premises, such as tissue banks, to store tissue from the living and the deceased (2). Tissue from the living means tissue taken while the person was alive, and this definition is kept after their death. Tissue which was taken from the living for the purpose of diagnosis and subsequently stored in a diagnostic archive can be used for research provided that [(3) (4)]:

- The donor has given consent to use the tissue for research; or
- The tissue and accompanying data are anonymised before transfer out of the diagnostic archive, and
- The tissue and accompanying data are transferred for use in a project that has been given a favourable opinion by an NHS REC.

Human tissue removed from the deceased must only be retained for use in research if appropriate consent has been given. Tissue released from diagnostic archives, or removed from the deceased, for the purpose of research, must be held on HTA-licensed premises, unless it is being used for an NHS REC approved project.

Researchers should be aware that no facilities are currently available within BU for the handling of tissue samples with a high probability of carrying infections agents. Please do not attempt to procure such material. If such samples have been received, please contact XXXXXXX who will dispose of the samples safely.

2. **Procedure**:

Human tissue obtained from NHS patients

For relevant material collected directly from NHS patients, researchers must follow the standard route for securing a favourable opinion from an NHS REC and obtaining permission from the relevant NHS Trust via IRAS. Consent should be obtained by using the "consenting NHS patients" PIS and consent form templates available on our website.

Samples removed during standard treatment (e.g. surgical procedures), or leftover after diagnostic testing, can be of considerable value for research. The value of these samples is further increased if they can be linked to information on the donor (e.g. age, medical conditions, treatment and outcome. If researchers require access to this type of sample, this should be done respecting the confidentiality of the donor and mitigating the risks of not being able to obtain consent. This is done by anonymising al identifiable data

Human tissue obtained from healthy volunteers (colleagues, students, general public)

Biological material obtained from healthy volunteer is subject to the same legal and ethical standards as those obtained from any other participant in research. Valid and freely given consent must be obtained and information must be provided on what samples will be used for, the risks of discovery of health related findings and how these would be handled, how their privacy will be protected and their right to withdraw. Particular attention must be given to the following:

- The possibility of a perceived obligation to participate
- Ensuring privacy of research results and
- Uncovering health related findings in situations where donors are likely to be known by those working on their samples

Independent ethical oversight of research involving tissue from healthy volunteers is required. This should be in the form of a favourable opinion from and NHS or University ethics panel.

Tissue samples removed from the deceased

Valid consent is a fundamental principle in the use of human tissue from the deceased for research. It is important that researchers respect any individual, religious or cultural beliefs when dealing with donations from a deceased person and due sensitivity should always be shown when approaching relatives to ask for consent. Relatives should whenever possible be given time to reflect before making their decision.

In situations when it is known that a potential donor's illness is terminal, a relationship can be established between the donor, their relatives and the research team before the patient dies.

This helps clarify the wishes of the donor to everyone involved. At this stage, the research team may secure written permission from the relatives to be contacted following the death of the potential donor to discuss donating tissues for research.

Human tissue obtained from other sources

- When relevant material is sourced from commercial suppliers, no ethical approval or consent is required. However a clear statement should be provided confirming that the material was obtained in a way which complies with the HTA.
- Acquisition of material from non-commercial sources (such as biobanks or Universities) must always be done under an MTA. You can download a template an MTA template on our website, which might require amending depending on the source and type of tissue. Fully signed MTAs must be forwarded to the ID for keeping.

Primary cells

The Human Tissue Act defines “relevant material” as “material other than gametes, which consists of or includes human cells”. The fundamental principle being that if a sample is known to contain even a single cell that has come from a human body, then the sample should be classified as relevant material. Cells obtained from human tissue such as blood are called primary cells and, in terms of the Human Tissue Act, there is no distinction between these cells and tissue. Cells which have grown outside the human body such as cell lines are not considered relevant material and are exempt from regulation.

Registering new tissue samples

For all tissue arriving to BU premises, please follow these steps:

- Completed consent forms must be stored by the CI in a locked metal cabinet or password protected device. Consent forms must be made available upon request for internal audits or external HTA inspections.

- All tissue arriving onto the facility must immediately be logged using XXXX.

- If primary cells are obtained from the human tissue, these should be recorded in XXXX

- All human tissue samples must be labelled clearly and legibly with the following information:
  Sample ID
  Cell/tissue type
  Date sample received/derived

- Sample aliquots should be held in a secure container, made of a material which provides physical protection at the temperatures. The outside of the container should be clearly labelled with the following information:
  Study name/identifier
  Cell/tissue type
  Start and end dates for the study
  Name of CI
  Details of any biological or chemical hazards

- Researchers should regularly check the labels of both samples and containers to ensure these have not been smudged or degraded. If they have been, this must be corrected immediately. If a sample becomes unidentifiable this must be reported as an adverse event using the adverse event reporting system.

- Transport of human tissue to BU human tissue facility must be conducted in accordance with the SOP for transportation. Human tissue must always be stored in approved locations within HTA licensed premises. Approved location will be clearly identified by XXXX and will include fridges, freezers, liquid nitrogen dewars, incubators and cold rooms. These facilities will be routinely monitored to ensure they remain fit for purpose. However research teams should consider routines of their own to keep these facilities in optimal conditions (such as cleaning rotas, defrosting) and agree contingency arrangements in case of an emergency.

3. References

(1) Human Tissue Act 2004: http://www.legislation.gov.uk/ukpga/2004/30/contents

(2) Human Tissue Authority code of practice and standards. Code E - Research: https://www.hta.gov.uk/hta-codes-practice-and-standards-0

(3) National Cancer Research Institute (NCRI)/Confederation of Cancer Biobanks: Biobank Quality Standard, collecting, storing and providing human biological material and data for research, version 1, 2014.

(4) Medical research Council (MRC) ethics series. Human tissue and biological samples for use in research: Operational and ethical guidelines. 2014.