UNIVERSITY OF SUSSEX

Code of Practice for the Acquisition, Storage and Use of Human Biological Material for Research.	
Version Number V 6.0	**Date: 17/07/2017**
Effective Date: 30/07/2017	**Review by: 30/07/2018**

Reviewed: Dr Georgios Giamas **Designation:** Designated Individual School of Life Sciences **Reviewed:** Dr Robert Fowler **Designation:** Persons Designate School of Life Sciences	**Signature**  	**Date** 11/09/2017 11/09/2017
Approved by: HTA Governance Committee	Signatures not sought as minimal changes	

Version	Date	Reason for Change
V2.0	28/8/2012	Change to License details and named PDs. Inclusion of addition glossary terms
V3.0	20/2/2013	Change to scope of CoP Minor corrections as requested by HTA inspector
V.4.0	15/7/2015	Change to reflect the update license to University wide
V.5.0	19/2/2016	Change to reflect the update to DI
V6.0	17/07/2017	Change to reflect the update to DI

Summary of Document

This document sets out the Code of Practice for the acquisition, storage and use of human biological material for research purposes, with particular reference to activities relating to the Human Tissue Act research licence 12119 and defines the responsibilities and accountabilities in relation to such activities.

Distribution

The authorised Code of Practice will be distributed to the licence holder, Persons Designate on the HTA licence and cascaded to other staff as appropriate.

This Code of Practice together with associated Standard Operating Procedures, will also be posted on the School of Life Sciences public website and made available to all research active staff.

Review

The Code of Practice will be reviewed annually or more frequently if deemed necessary by the HTA Governance Committee.

Implementation

The Designated Individual (DI) on HTA research licence 12119 is responsible for ensuring that this code of practice is implemented across all related sites. The DI will, with the approval of the HTA Governance Committee, delegate the task of implementing this code of practice to the Persons Designate.

1. Introduction

The purpose of this Code of Practice is to ensure that all staff undertaking research using human specimens do so within the framework of the Human Tissue Authority (HTA) Licence and know and comply with relevant sections of the Human Tissue Act (2004), HTA licensing conditions, Codes of Practice and related policies.

The University has a duty of care to any person who has consented to the use and storage of their biological specimens for research to ensure that the material is treated with respect and is handled in accordance with the terms of the consent given and the appropriate legislation.

2. Definitions

***Adverse Incident**:* HTA definition: Any event that:

- caused harm or had the potential to cause harm to staff, patients or visitors;
- any event that led to or had the potential to lead to a breach of security of the premises and the contents contained therein;
- any event that caused harm or had the potential to cause harm to stored human tissue (including loss);
- any other event that gives rise to an internal inquiry.
- any breach of the HT Act or the Codes of Practice

***Anonymisation*:** samples or data have had any identifying information removed, such that it is not possible for the researcher using them to identify the individual to whom they relate. They may be:

- Linked anonymised – Specimens are fully anonymous to the people who use them but remain coded such that an appropriately authorised person could link them back to the person from whom they came.
- Unlinked anonymised -the link between the specimen and the person from whom it came has been irreversibly broken.

***Appropriate consent**:* consent as defined by the Human Tissue Act and the guidance from the Human Tissue Authority in Code of Practice A: Consent.

Designated Individual: Person under whose supervision the licensed activity is authorised to be carried out.

***Donated material/tissue**:* human biological material that has been removed with appropriate consent as set out in section 1 of the Act.

HTA: Human Tissue Authority, the independent body set up under the Human Tissue Act (2004) to regulate the removal, storage, use and disposal of human bodies, organs and tissue for a number of “Scheduled Purposes”.

HTA Governance Committee: is responsible for developing policies and procedures and to ensure operational practise is compliant with the Human Tissue Act, HTA codes of practice and licensing requirements.

Human Biological Material: For the purposes of this policy Human Biological Material shall refer to material that has come from a human body and consists of or includes human cells (the definition of 'relevant material' used in the Human Tissue Act (2004) section 53).
Human Tissue Act (2004) *["The Act"]:* legislative framework covering the uses to which human biological samples can be put. Material not covered by the Act include hair and nail of a living person, gametes and embryos, which are separately regulated by the Human Fertilisation and Embryology Act (1990), established cell lines, human material created outside the human body or rendered acellular by processing (eg serum, plasma, cell free supernatants, DNA).
HTA Licence **- Research**: Held by the University - licence number 12119
Persons designated: Named person to whom the licence extends and who provides advice, direction and guidance to those at the site.
Principal Investigator: The principal investigators are responsible for all aspects of their research activity including the acquisition, storage, use and disposal of human biological material. They must be familiar with all current requirements and procedures relating to research and the use of human biological material as defined in this Code of Practice
REC: Research Ethics Committee (REC) established under and operating to the standards set out in the governance arrangements issued by the UK Health Departments; or an ethics committee recognised by United Kingdom Ethics Committee Authority (UKECA), to review clinical trials of investigational medicinal products under the Medicines for Human Use (Clinical Trials) Regulations 2004. A University ethics committee is not, for the purpose of the consent exception considered to be a recognised research ethics committee.
Researcher/research staff: All staff involved in research must comply with all relevant SOP's, policies and standards of good practice to ensure compliance with the law, HTA licensing conditions, codes of practice and the Research Governance Framework
SOP: Standard Operating Procedure is a written document or instruction detailing all steps and activities of a process or procedure so that there is uniformity of a specific function
Surplus Human Biological Material: refers to material that has been removed from a patient for the primary purpose of diagnosis, treatment or a specific research project and is no longer required for that purpose.

3. Scope

The scope of this Code of Practice applies to the collection, storage, use and management of all specimens of human biological material for research purposes collected since 1st September 2006. It also applies to the storage, use and management of all specimens of human biological material for research purposes collected before 1st September 2006

It is the responsibility of all staff working with human material at this HTA licence site to know and comply with the requirement of the licences, the law and this policy.

4. Governance

The HTA Governance Committee will develop policy in relation to the Act, HTA licence conditions and codes of practice to ensure that anyone working under licence 12119 can comply with current legislation and guidance. The HTA Governance Committee is accountable to the University HTA Coordination Group.

HTA Governance Committee

- Georgios Giamas (Designated Individual and PD – Life Sciences)
- Kim Bowman (PD – BSMS)
- Jenny Rusted (PD – Psychology)
- Heather Fawcett (PD – GDSC
- Lisa Woodbine (PD – GDSC)
- Robert Fowler (PD – Life Sciences)

5. Research Approvals

Research using human biological material cannot be carried out unless the project has been approved by an appropriate Research Ethics Committee (as defined by HT Act 2004, Statutory Instrument 2006 No 1260 Section 1 (2)).

6. Consent

Human biological material can only be acquired, stored and used for research if appropriate consent has been obtained. (For exceptions see: 7. Use of surplus diagnostic specimens).The giving of consent must be a positive act, the absence of refusal is not evidence of consent.
Anyone removing, storing or using material in circumstances for which the HT Act requires consent must be satisfied that consent is in place.
It is the principal investigator's responsibility to ensure that appropriate consent procedures are in place as well as Service Level Agreements in the case of a third party taking consent.

If under the NHS, a person's agreement or refusal to consent to the donation, storage or use of tissue for purposes under the Act must not affect the investigation or treatment that s/he receives. If the person being approached is a member of the University staff or student body their agreement or refusal must not affect their management or supervision whilst at the University.

Deceased patients

Consent is required for the removal, use and storage of relevant material from the deceased for **ALL** scheduled purposes listed in HT Act Schedule 1 (parts 1 and 2).
Explicit consent must be obtained separate from the consent for post mortem examination to remove organs or tissue from the deceased for the primary purpose of research.

7. Acquisition of Human Biological Material

It is the responsibility of those collecting/acquiring human biological material for research purposes to know and follow the local procedures.

Use of surplus diagnostic specimens

Specimens surplus to diagnosis and held in diagnostic/teaching archives can be used for ethically approved research with the donor's consent; unless it was stored prior to implementation of the HTA Act on 1 September 2006, in which case consent is not required, as it is regarded as an "existing holding".

Diagnostic tissue can only be released for research under the following circumstances:

- When the patient has given consent for use of their tissue in research (the preferable scenario);

Where tissue that has not been consented for research (other than existing holdings) can only be released if it is from a living person, and

- the researcher is not in possession, and not likely to come into possession of information that identifies the person from whom it has come;
  AND
- where the material is released by a research tissue bank with generic ethical approval from a REC for research within the terms of the approval
  OR
- it is to be used for a specific research project approved by a REC.

Use of DNA/RNA from human biological material

It is an offence to have any bodily material (i.e. material which has come from a human body and which consists of or contains human cells) with intent to analyse the DNA in it without qualifying consent, subject to certain exceptions. This section applies to any type of analysis of DNA as defined in genetic research.

8. Storage of Human Biological Material

Material acquired for a specific project

All material collected will be entered and tracked onto the research database until its disposal and any specific requirements detailed at the time of consent. If, during the time of the project, material that had been obtained with project specific consent is needed to be stored for unspecified future use, consent will need to be re-obtained.

Material acquired for unspecified future use

Surplus human biological material can only be stored for the primary purpose of future unspecified research (i.e. in a research tissue bank) under the terms of an HTA licence. Human biological material can only be stored for future unspecified research purposes if there is consent from the donor to do so.

Specimen tracking

A record within the research database must be made of all human biological material collected for the purpose of research. The exception to this is where samples are made acellular or transferred to another recipient within 5 working days. The database will contain information on consent, ethics approval, storage location and fate in order that an audit trail is maintained. Transfer of samples to other institutions must also be recorded on the research database

Custodianship

The legal responsibility for the use and management of human biological material for research purposes lies with the Designated Individual on the HTA Research Licence.
As the corporate Licence Holder, the University of Sussex will have the formal responsibility for custodianship of the sample and has a responsibility to the donor under the terms of the consent to fulfil the donor's intention.
The University of Sussex and the Designated Individual will delegate the day-to-day management and responsibility for storage, tracking, safe-guarding donors' interest, control of use, disposal and transfer of the donated material to the local principal investigators of the ethically approved research project or tissue bank for which the sample was acquired.

9. Transfer of material

Human biological material can only be transferred to another organisation for a specific ethically approved research project and under the terms of the consent.
An agreement has been drawn up by the Contracts & Intellectual Property office and all human biological material that leaves the University of Sussex HTA licence sites must do so in accordance with the current SOP; being appropriately anonymised where practicable unless consent for a specific research project has been given, in which instance an identifier for the samples agreed between the University of Sussex and the receiving institution must be used. The transfer of the material must be logged on the appropriate laboratory information management system.

10. Disposal

The Human Tissue Authority states that as best practice all human tissue should be disposed of by incineration and separate from other clinical waste.

All human biological material will be disposed of as human tissue waste as detailed in the relevant SOP, and in line with the consent given. Detail of when and why the material is disposed of must be recorded in the research database.

11. Confidentiality

Confidentiality of donor/patient information is a high priority and every effort must be expended to ensure it. The University position on confidentiality and research governance is covered in documents within links below:
http://www.sussex.ac.uk/res/documents/code.pdf
http://www.sussex.ac.uk/res/documents/research_governance_code_of_practice.pdf

12. Adverse events

All adverse incidents involving the collection, transport, storage, use or disposal of human biological material for research purposes must be reported in accordance with the SOP for Adverse Incident Reporting.
Adverse incidents involving human biological material at any Sussex University sites must be reported and investigated through the incident reporting system and be notified to the DI so that they can feed into the School of Life Sciences and Psychology Management Committees.
All adverse events will be logged and any required changes to policies, risk assessments and standard operating procedures will be instituted by DI in consultation with the PDs.

13. Risk management systems

All activities relating to the acquisition, storage, use, transportation and disposal of human biological material requires risk assessment. This should be performed and recorded according to the University policies and procedures. The main criterion for risk assessment will be the integrity of the human biological material and all points made in the risk assessments will be clearly reflected in the standard operating procedures which will be recorded in the same manner as the risk assessments. These assessments will be reviewed every two years.

14. Complaints

During the consent process all donors will be made aware of our complaints procedure. A complaints form will be readily available and will be displayed on the School web pages. Complaints will be submitted to the DI who will respond after consultation with PDs and PIs. The complaint and its subsequent action will be reported to the relevant committee. Any required changes in policy, risk assessment or standard operating procedure will be instituted by the DI in consultation with the PDs.

15. Training

Basic induction into the use of human biological material for research and human tissue governance is included in Safety Induction which is provided to all new staff and post graduate students, will be provided by the PD or the DI at the commencement of any new employment contract.

16. Premises

Premises used for the storage and use of human tissue will be secure, out of hours security as well as general premises maintenance will be the responsibility of the University of Sussex. All areas required for the discharge of activities relating to the use of human tissue will be risk assessed. General health and safety issues will be the responsibility of the University of Sussex.

17. Equipment

Research and technical staff will be supplied with the appropriate equipment, including personal protective equipment in order to minimise the risk of contamination and to avoid compromising the integrity of human tissue. All equipment will be regularly (annual or bi-annual) calibrated, validated and serviced. Records of this will be securely stored.

18. Receipt and distribution of local and national alerts

National Alerts from the HTA will be received and subsequently circulated to staff and students working with human tissue by the DI.

More general alerts regarding issues such as local power loss or fire/flood will be provided by the Estates or Health and Safety Offices to the DI who will circulate this information to staff and students working with human tissue.

19. Contingency plans

Every School that uses human tissue must have contingency plans in place that take into consideration the need to protect human biological material from damage or loss.

Freezer failure

All ultra low temperature freezers are alarmed and connected to automatic diallers where the appropriate person is informed. In the case of a failure, samples will be immediately moved to alternative freezers which have been identified in existing local emergency plans, according to the relevant standard operating procedure.

Equipment failure

In this case, alternative similar equipment for the procedure should be found. In the case of biological safety cabinet failure, the procedure should be delayed until an appropriate Cat II cabinet is located.

Site failure

In the case of catastrophic site failure, the relevant University of Sussex policies on work continuation will be put into practice.

20. Monitoring and auditing

We are required to comply with the HTA licensing conditions and Codes of Practice in order to operate within the law and maintain the confidence of the public and patients. The HTA has a duty to inspect licensed premises and activities on a regular basis to ensure this is being done. Regular internal auditing and monitoring of consent, tissue tracking, storage, incident reporting and tissue disposal will be led by the HTA Governance Committee.