BU RDS SOP 024 V1

| Title: Human Tissue for Research Purposes | |
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| Approver: University Research Ethics Committee | |

## 1. Scope

This Standard Operating Procedure (SOP) describes the requirements and procedures surrounding the collection and storage of human tissue for research purposes.

## 2. Responsibilities

The *Clinical Governance Advisor (CGA)* is responsible for advising researchers as to whether their project requires NHS Research Ethics Committee (REC) approval, and what to consider with regard to the Human Tissue Authority's guidelines. They are also responsible for advising on study protocol content and informed consent forms.

The *Chief Investigator (CI)/Researcher* if intending to use human material in their research, is responsible for ensuring that they familiarise themselves with this SOP prior to submitting their Online Ethics Checklist. They should also adhere to the Human Tissue Authority (HTA) Codes of Practice, adopting any new procedures or amending any existing procedures when new guidance is released. The Investigator is also responsible for the content of study documents, relating to human tissue collection, use and storage. See section 3.8.

## 3. Procedure

Human Tissue Authority (HTA)

The HTA was created by Parliament as a non-departmental public body of the Department of Health. Their purpose is regulate organisations that remove, store and use human tissue for the purposes of research, medical treatment, post-mortem examination, education and training, and display in public.

The Human Tissue Act defines *relevant material* as any material from a human body that consists of, or includes, cells. This includes blood (except where held for transplantation). Hair and nail from living persons are specifically excluded, as are gametes and embryos outside the body, which are covered separately by the provisions of the Human Fertilisation and Embryology Act.

Relevant material under the act consists of: bile, blood, bone marrow, bones/skeletons, brain, breast milk, buffy coat layer, cerebrospinal fluid, cystic fluid, eggs (ova), faeces, fetal tissue, fluid from cystic lesions, hair (from a *deceased* person), join aspirates, mucus, nails (from a *deceased* person), nasal and bronchial lavage, non-blood derived from stem cells, non-fetal products of conception (i.e. amniotic fluid, umbilical cord, placenta and membranes), organs, pericardial fluid, platelets, primary cell cultures, pus, saliva, skin,

sputum (or phlegm), stomach contents, teeth, tumour tissue, umbilical cord blood stem cells and urine.

### 3.1 Research tissue banks

If a research tissue bank holds a HTA licence for research then ethical review is not required. An application for ethical review would be voluntary.

If the research tissue bank is planning on distributing tissue to external researchers, then an application to the REC can be made for *general ethical approval* for the research programmes. The REC would then set out conditions, such as only supplying anonymised human tissue.

### 3.2 When a HTA licence is not required

A licence is not required if the human tissue is from a person who died prior to 1st September 2006, and at least 100 years have elapsed since their death.

#### *3.2.1 Temporary storage of human tissue*

Under the Human Tissue Act, *storage* does not include storage prior to transportation (human tissue held for hours or days, no longer than a week, before being transferred to another organisation). In this case, a HTA licence is not required, however if the researcher holds the human tissue for a short period for the purposes of a project, and to conduct analysis before discarding the material, then this is classed as research. This storage would require a HTA licence or ethical approval for the life of the research project.

#### *3.2.2 Extraction of DNA or RNA*

If human tissue is being held for the purposes of extracting DNA, RNA, or other subcellular components that do not constitute *relevant material*, then a licence is not required. *However,* if DNA is being extracted from acellular material, then it will require REC review.

Ethical approval is a legal requirement where the bodily material from a living person has been stored with the intention of conducting DNA analysis, without consent from the person whose body manufactured the DNA. Similarly, ethical approval would be required if identifying data is held with the DNA sample.

#### *3.2.3 Whole blood sampling*

A HTA licence is not required when whole blood samples are taken and tested immediately, with remaining material disposed of. Similarly, no licence is required if the sample was made acellular immediately, or if samples were taken over a period of days, and then made acellular on the last day, with the serum stored for research purposes.

No licence is required when a study has received approval from an NHS REC, even if the study protocol requires whole blood sampling. On the other hand, a licence is required if blood samples are taken from healthy volunteers for a study that does not have approval from a recognised NHS REC.

*3.2.4 When a study has received ethics approval from a recognised REC under the Human Tissue Act,* i.e. a committee recognised by the United Kingdom Ethics Committee Authority

under the Clinical Trials Regulations, or a Research Ethics Committee (REC) recognised by the health departments in England, Wales or Northern Ireland. University Research Ethics Committees/Panels are not authorised to grant approval for this activity.

Under the Human Tissue Act 2004, tissue and cells may be stored without a licence for a research project, provided the project has received appropriate ethics approval.

Samples held for a project that has been granted NHS REC approval may be held for up to one year after the end of study declaration, for the purposes of analysis or verification of the research data. This activity should be detailed in the application made for ethics approval.

Consent is not required to store and use the tissue from the living, for a project with ethical approval, if the material has been anonymised.

3.3 Imported tissue

3.3.1 Under the Human Tissue Act 2004, importing and exporting human tissue is not a licensable activity. However, this does not mean that storing and using imported tissue is exempt from licencing requirements, unless it is for a specific project that has obtained NHS REC approval.

3.3.2 Preferably and if possible, imported tissue should be stored in a licensed establishment, and if this is achievable, NHS REC approval would not be required to undertake research.

In applying for NHS REC if required, the researcher should provide assurances that the human tissue was obtained ethically and in accordance with any legal requirements of the donor country, including specific consent for research if suitable.

3.4 Approvals required before conducting the research

3.4.1 Depending on the type of research you are doing involving human tissue, you will need different approvals. Health Research Authority[1] (HRA) approval is required for all project-based research, taking place within an NHS setting.

If you are creating a research tissue bank or biobank (stored for potential research use beyond the life of a specific project), then you *will not* need HRA approval, but *will need* NHS REC, a Human Tissue Authority (HTA) licence and registration in the UKCRC Tissue Directory.

If you are conducting research involving previously collected, non-identifiable tissue samples, then NHS REC approval *is not* required:

- as long as consent for the research has been given;
- the material will be held on premises with a HTA licence;
- no new samples will be removed, stored or collected;
- and, you are not using any identifiable information that is held with the samples.

[1] Please note, as of June 2018, HRA approval is now HRA and Health and Care Research Wales (HCRW) approval

3.4.2 If however consent for the research has *not* been obtained, then ethical approval would be required. HRA approval should be sought, as required for all health-related research.

Additionally, NHS RECs will accept applications for research involving human tissue not collected from NHS patients.

3.5 Approvals for future projects

3.5.1 When wishing to collect human tissue for a specific project, but also wishing to store the material for future projects, the researcher should apply to the NHS REC for ethical review of the initial study, using IRAS. The ethical approval will then give them the authority to store the tissue for the duration of the specific study. Before the end of this study, if the human tissue has ongoing value, then the one of the following must be done, so as to make storing the tissue for further research lawful:

- apply for ethical approval of a new project;
- set up a research tissue bank and obtain a HTA licence;
- transfer the human tissue to a licensed establishment.

3.6 Consent for the storage and use of human tissue

3.6.1 Consent is not always legally required to store and use human tissue for research. There are a number of exceptions under the Human Tissue Act, namely:

- tissue which is an “existing holding”, i.e. it was already held before 1 September 2006;
- tissue which has been taken from a living person AND the researcher is not able to identify the person AND the research project is ethically approved by a REC;
- imported tissue.

3.6.2 Even though consent is not *legally* required, human tissue should not be used without regarding ethical considerations. Researchers should still consider whether it is ethically appropriate to obtain consent and if practical, should respect the views of the deceased person or of their relatives before using the tissue.

3.6.3 In the case of *removing* human tissue from the deceased for research, appropriate consent is *always* required. Consent is likewise required when it is intended to remove human tissue from the living. If it is intended to store and use the human tissue for research, specific consent for research should be obtained at the same time as consent for the collection of the tissue.

3.7 Exporting human tissue for overseas research

3.7.1 There is no legal requirement for licensing or gaining ethical approval for this activity, but researchers may make voluntary applications to an NHS REC if preferred. Within this review, the NHS REC will concentrate solely on the activities to be conducted in the UK, and arrangements surrounding informed consent. Documented agreements must be in place that ensure that human tissue exported from England, Wales and Northern Ireland are used in accordance with the consent the participant has given.

3.7.2 When seeking consent from donors, it is good practice to fully inform them of plans to export their human tissue outside of the UK, and to reiterate the use of material in relevant and valid scientific research by overseas collaborators. Materials for export should be obtained, used, handled, stored, transported and disposed of in accordance with the consent the participant has given.

3.8 Investigator responsibilities

3.8.1 Prior to the project starting, the Investigator should consult this SOP prior to completing and submitting their Online Ethics Checklist, so that they answer the filter questions appropriately, and identify the correct approval bodies for their research project.

3.8.2 The Investigator should ensure that their study protocol contains the following information:

- the source of the tissue samples to be used for their research;
- consent procedures for use and storage of the donated material for research purposes;
- arrangements for anonymisation of tissue samples, if applicable;
- storage arrangements for tissue samples during *and* after the project has ended;
- arrangements for the recording of collection and use of the material.

3.8.3 In addition to the study protocol, Investigators should ensure that their Participant Information Sheet(s) (PIS) adequately set out the requirements and intentions of the researcher in collecting, storing and using their human tissue, as well as how they will collect it and the nature of the tissue sample to be donated, e.g. collecting a surplus paraffin block during routine surgery.

The PIS should state:

- whether new tissue samples will be obtained as part of the research, i.e. specifically for the research;
- whether the tissue samples collected are in addition to a clinical procedure;
- whether the researcher wishes to access existing stored samples;
- security measures in place for the collection, use and storage of samples;
- whether there is intended future use of their material, which as yet is not definite – in this case, a separate or two-part consent form is recommended, and it should be made clear as to whether further NHS REC approval will be sought;
- who will have access to the tissue sample(s);
- confidentiality measures for the current study, and concerning any storage for future studies;
- procedures for the destruction of the tissue sample(s) after research use;
- whether tissue samples will be transferred outside of the UK.

3.8.4 Explicit consent must be sought via the Informed Consent Form for the use of participants' tissue. Investigators or a delegated staff member must document this consent in the medical record, alongside a copy of the consent form and the PIS, keeping the original consent form in the Investigator Site File (ISF).

3.8.5 Investigators should maintain a record of the tissue samples obtained during the research study, so as to track the origin, storage location, use and final destination of the material. The record must be kept in the ISF and samples stored as described in the approved ethics application, or in a HTA licensed tissue bank.

3.8.6 The Investigator should inform the NHS REC of the end of the study, and ensure that any tissue samples remaining following study completion are destroyed according to *local policy* and in accordance with NHS REC approval and HTA Codes of Practice. The samples may be transferred to a HTA licensed tissue bank, should the Investigator wish to retain any remaining tissue samples following the closure of the research project. A list of licensed establishments can be found here - https://www.hta.gov.uk/establishments

3.8.7 Should the Investigator wish to involve BU in importing or exporting human tissue, then they must do so under the terms of a Material Transfer Agreement. If the research study is classed as *non-commercial*, then this is covered within the HRA document entitled the *Statement of Activities*. If this requirement becomes necessary once the project has gained external approvals, then a physical Material Transfer Agreement should be drafted and signed before any activity takes place. The CGA will offer guidance on how best to proceed with regard to agreements for material transfer.

## 4. Abbreviations and definitions

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| CGA | Clinical Governance Advisor |
| CI | Chief Investigator |
| DNA | Deoxyribonucleic Acid |
| HRA | Health Research Authority |
| HTA | Human Tissue Authority |
| ISF | Investigator Site File |
| NHS REC | National Health Service Research Ethics Committee |
| PIS | Participant Information Sheet |
| RNA | Ribonucleic Acid |
| UKCRC | UK Clinical Research Collaboration |

## 5. Related documentation and references

Directory of HTA licensed establishments - https://www.hta.gov.uk/establishments
HRA guidance regarding research tissue banks - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-tissue-banks-and-research-databases/

Human Tissue Authority. (n.d.). [online] Available at: https://www.hta.gov.uk/sites/default/files/Supplementary_list_of_materials_200811252407.pdf [Accessed 13 Jul. 2018].

Legislation.gov.uk. (2018). Human Tissue Act 2004. [online] Available at: http://www.legislation.gov.uk/ukpga/2004/30 [Accessed 12 Jun. 2018].

Details of Designated Individual: [when known]