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The definitive version of all University of Leicester (UoL) Human Tissue Authority (HTA) Standard Operating Procedures (SOPs) appear online, not in printed form, to ensure that the up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Research Governance Ethics and Integrity (REGI) Website.

SOP: HTA-A1003-UoL

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Development and Approval Record for this Document

Role	Name	Job title	Signature	Date
Author	Amanda Sutcliffe	HTA Monitoring Officer		08/02/2021
Reviewer	All members of the College of Life Sciences Human Tissue Governance Committee	College of Life Sciences Human Tissue Governance Committee	N/A	N/A
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Background

When applying for project specific Health Research Authority (HRA)/Research Ethics Committee (REC) approvals through the Integrated Research Application System (IRAS), the project-specific application form may not be used to seek open-ended approval for the use of stored tissue in future research programs. Nor is it permitted to submit substantial amendments to approved projects in order to use the tissue for another project with a different set of research questions.

Where a researcher makes a project specific application but then plans to store the material beyond the life of the project for use in future projects, there are a number of options available to them.

This SOP will outline the requirements for the long terms storage of the samples pending use for future research projects as per the IRAS option: storage by research ethical approval for use in another project.

Purpose and Scope

This SOP has been produced in accordance with the Human Tissue Act 2004 and the Codes of Practice issued by the HTA, in accordance with the HRA regarding sample storage of relevant material. The SOP outlines the expectations of samples in long term storage once project specific REC approvals have expired.

Definitions:

AB	Adrian Building
CI	Chief Investigator
DI	Designated Individual
GGH	Glenfield General Hospital
LGH	Leicester General Hospital
HB	Hodgkin Building
HRA	Health Research Authority
HWB	Henry Wellcome Building
HTA	Human Tissue Authority
IRAS	Integrated Research Application System
LRI	Leicester Royal Infirmary
MHRA	Medicines and Healthcare products Regulatory Authority
PD	Persons Designated

PI	Principle Investigator
REC	Research Ethics Committee
REGI	Research Governance Ethics and Integrity
RKCSB	Robert Kilpatrick Clinical Sciences Building
RTB	Research Tissue Bank
SOP	Standard Operating Procedure
UoL	University of Leicester

Roles and Responsibilities

Staff involved in setting up and conducting research involving human tissue, which include: Chief Investigators (CI), Principal Investigators (PI) Trial Managers/Co-ordinators, Laboratory Personnel, Research Nurses, Managers and Clinical Trial Administrative staff and Students.

It is the responsibility of the Designated Individual (DI) to ensure that suitable practices take place within the licensed establishment that comply with the HTA Codes of Practice. The DI must act as a gatekeeper for any material that is to be reported on the UoL HTA research licence.

It is the responsibility of the HTA Monitoring Officer to ensure when a study comes to an end, that guidance is given to the appropriate staff to ensure all HTA applicable processes are followed. In addition, the HTA Monitoring Officer is responsible for ensuring this SOP remains fit for purpose taking into consideration any changes in any legislation regarding regulatory requirements.

It's the responsibility of the Persons Designate (PD) to assist the DI in implementing and adhering to the governance processes.

Procedure to follow

This SOP outlines the processes required to be followed at the end of the study where the CI/PI would like to retain the material beyond the scope of the original research project, where the material has the relevant consent for future research purposes, but the remaining material will not be governed under the ethics of an Research Tissue Bank (RTB).

End of study definitions

Upon completion of a project specific research study (the end of study definition as defined in the IRAS and protocol), in most cases, will be the date of the last visit of the last participant or the completion of any follow-up and data collection as described in the protocol.

At the end of the study you will have to declare the end of the study using the appropriate form(s) and providing any applicable final reports to the appropriate body(ies) i.e. REC/ Medicines and Healthcare products Regulatory Authority (MHRA) within defined timelines (usually within 12 months of study completion).

At the end of the project, the researcher may make a further project specific-application that must be submitted no later than the date on which the first project ends (as defined in the protocol), otherwise the continued storage of the tissue would require a storage licence from the HTA.

Samples may be held after the declaration of the end of the trial, for analysis or verification of research data for up to one year. After this period legal authority to hold any human tissue under the ethical approval will expire.

To ensure that any continued storage is lawful, the tissue must either be held in premises that are covered by a licence from the HTA or an application should be made for ethical approval of another project before the favourable ethical opinion of the existing project expires. Alternatively ethical approval can be sought in the form of a RTB.

Research Licence 12384 Geographical location

Any relevant material that is to be stored beyond the original ethical approval, must be relocated to a building that is covered by the HTA research licence for its long term storage. All samples being transferred to the HTA licence should follow the application process as documented in SOP *HTA-A1001.*

The HTA Research licence covers the Glenfield General Hospital (GGH), Leicester General Hospital (LGH), the Robert Kilpatrick Clinical Sciences Building (RKCSB) located at the Leicester Royal Infirmary (LRI), UoL Main Campus buildings: Henry Wellcome Building (HWB), Hodgkin Building (HB), Maurice Shock Medical Science Building (MSB) and the Adrian Building (AB).

It is important to be aware that any relevant material to be stored beyond the specific research project requires an application for transfer to the UoL HTA licence detailed in SOP *HTA-A1001* and in conjunction with SOP *HTA-A1008* and *HTA-A1009.*

Future use of samples

Once localised in a HTA compliant area, the samples must not be used without further ethical approval being sought, either by a new project specific application via IRAS or alternatively, an ethically approved RTB.

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

Review Record

Date	Issue Number	Reviewed By	Description Of Changes (If Any)

Distribution Record:

Date	Name	Department	Received Y/N