DIVISION OF RESEARCH AND INNOVATION

Joint Research and Development Office

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Title: Human Tissue Act (HTA) Compliance Management	
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	Name	Position
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1. Scope

This SOP is applicable to all the research studies sponsored by Great Ormond Street Hospital (GOSH) /GOSH UCL Institute of Child Health (UCL-ICH), and all external sponsors. The Human Tissue Act (2004) was issued to make provision for the regulation of removal, storage, use and disposal of human bodies, organs and tissue for a number of scheduled purposes including research. The Act came into force on 1st September 2006. Consent is the fundamental underlying principle of the HTA which aims to ensure that all human tissue is managed in an ethical manner. *Consent must be voluntary and informed.* Consent can be given for specific purposes (such as a specific research project) or it can be generic (broad consent for unspecified research/ length of time).

Material covered by the Human Tissue Act:

The Human Tissue Act refers to relevant material which is “material, other than gametes, which consists of, or includes human cells.” Examples listed below:

Relevant Material	Non-relevant material
• Cell deposits • Tissues on slides • Skin samples (biopsies) • Bone or bone marrow • Organs • Whole blood • Faeces, urine, saliva, nasal lavage	• Embryos and gametes • Material created outside the human body • Hair & nails from living people • DNA • Excretions/ secretions rendered acellular e.g. serum • Cell lines

Further information on 'relevant material' can be found at:
www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm

Sources of relevant material (for research):

All relevant material obtained for research must be traceable to ensure that appropriate documented consent (or documented consent exemption) has been obtained for its use and that it is being used in accordance with any conditions from the provider.

Where such material is transferred between organisations and where there is not already a service level or research agreement/ purchase agreement, a material transfer agreement (MTA) may need to be put in place.

There is a service level agreement for the transfer of human material between UCL-ICH and GOSH for research in accordance with the Human Tissue Act. This SLA is updated biannually in April.

MTA's are legal contracts that govern the exchange of such material between organisations by documenting (amongst other things) the scope of material use, confidentiality, research publication, and Intellectual Property (IP) for the parties supplying, receiving and using the tissue. Guidance on developing MTAs can be obtained from the Contracts team in the Joint R&D Office (for GOSH) and UCL Business (for UCL).

Sources of Human Tissue for research use:	Implications for researchers
Collecting Human Tissue from NHS patients	These studies require **Health Research Authority (HRA) approval** which includes a **NHS Research Ethics Committee** review. This is facilitated by completing the **Integrated Research Application System** (IRAS) form online.
Collecting Human Tissue from Volunteers	These studies require approval from a Research Ethics Committee (REC). For UCL-ICH studies, although approval can be obtained from the UCL University REC**, we would recommend that investigators request an opinion from an NHS REC** instead**:** - **UCL-REC is not a recognised REC (it is not registered with UKECA) and so the storage of relevant material for research also would have to come under governance of a HTA licence. This would require the permission of the Designated Individual (DI).** - **Applying for an opinion from an NHS REC would mean that the storage of relevant material for research will not come under the governance of an HTA licence until the period of the REC approved research project ends. If the project is not NHS based a review by a**

	NHS REC can still be applied for without application for HRA approval.
Purchasing from a Commercial Supplier (including import of tissue)	Care should be taken in ensuring all relevant material has documentation (available for inspection by the HTA) to demonstrate both reputable source and consent. **Generic REC approval is not always in place and so researchers may need to apply for their own project specific REC approval**. Cell lines can also be purchased from commercial suppliers however these are not HTA relevant and would not require a project specific REC approval. Care should also be taken in ensuring all material has documentation to demonstrate both reputable source and consent (if necessary). It should be noted that if cells are fully divided into cells lines researchers can use them for their different future projects without consent. In terms of research, the consent provisions of the HT Act do not apply to imported material. However, the HTA considers it good practice for there to be mechanisms in place to provide assurance that the tissue has been obtained with valid consent. The import of relevant material may need to be stored under a research HTA licence if stored for research.

Obtaining from a Research Tissue Bank	Tissue banks usually have **Generic NHS REC approval** in place for use of tissue in research. In this case researchers are **not** required to apply for their own NHS REC approval to obtain and use the tissue from the bank in their research. If the Research Tissue Bank **does not have Generic NHS REC approval** then researchers are required to apply for their own NHS REC approval to obtain and use tissue from the bank. It is a requirement to check initially whether the Research Tissue Bank has **Generic NHS REC approval** as above.

Since human tissue is used and stored at both UCL-ICH and GOSH both organisations hold their own Human Tissue licenses to cover the storage of human tissue[1].

UCL is the corporate licence holder for the licence that covers UCL-ICH human tissue storage for research purposes. UCL has a range of SOPs and policies which UCL-ICH staff must use. There are a number of UCL working groups and meetings to which the DI is invited including a meeting of UCL DI's twice a year. Quarterly meetings are held between the R&D Office, the UCL-ICH DI and DP's.

GOSH holds a research licence and monthly meetings are held between the R&D office, the GOSH DI and DP's. Although diagnostic archives fall outside the remit of the HTA licence, material from diagnostic archives may be used for research with appropriate ethical approval and anonymisation. At the outset of the study it must be clarified with the clinical lead for the laboratory holding the archive whether material will be returned to the archive at the end of

[1] Storage of human tissue other than for specific ethically approved research studies

the study or discarded by the researcher. Storage conditions of the sample during the study may need to be taken into account. It should be noted that DNA samples can be used for research without consent if they are from the living (at the time the sample was taken), are anonymous to the researcher; and to be used in research with a NHS REC approval.

This document is for use by the GOSH/ UCL-ICH R&D Office as an SOP when:

- Reviewing research projects involving the use of human tissue – to identify the source of human tissue used in research, and plans for its storage or disposal following the completion of ethically approved research.

- Supporting the work of the GOSH and UCL-ICH Designated Individual (DI) and the team of Persons Designate (PD) who are responsible for conformance with the Human Tissue Act – by identifying collections of human tissue remaining after an ethically approved research project has ended.

- To advise on the appropriateness of returning remaining tissue to the GOSH diagnostic archive and appropriate GOSH tissue banks.

2. Purpose

The role of the R&D Office is to:

1. Review and issue R&D approval (or confirmation of site participation for HRA approval studies) for research that uses relevant material.
2. To contact researchers nearing the end of approved research studies to ascertain their plans for any remaining human tissue and pass on the information to the GOSH/UCL-ICH DI for action – if necessary. Any correspondence is documented on ReDA and in the R&D office e-mail archive.
3. To advise on the appropriateness of returning remaining tissue to the GOSH diagnostic archive and appropriate GOSH tissue banks.

3. Definitions/Abbreviations

N/A

4. Responsibilities

The Designated Individual (DI) at each organisation is the person with statutory responsibility under the Human Tissue Act. They have a duty to ensure that people working under the licence follow suitable practices.

The Persons Designate (PDs) at GOSH/UCL-ICH have a role in supporting the DI and the DI is responsible for appointing the PD's. The Unit PD's assist the DI in supervising the licensable activities by ensuring processes and procedures are followed in GOSH/UCL-ICH departments.

The oversight and management of Human Tissue (relevant material) storage at GOSH and UCL-ICH is the responsibility of the respective Designated Individuals (DI's) at GOSH and UCL-ICH.

5. Procedure

5.1. Reviewing a research project involving Human Tissue

Reviewing & approving a research project involving Human Tissue.	
1. Review research project and identify the source of human tissue	a. Obtaining tissue from NHS patients or volunteers
	b. Using tissue already collected under an existing ethics approval
	c. Purchase material from a commercial supplier
	d. Obtain tissue from a licenced tissue bank

2. Check for REC approval/ provide advice on making an application for HRA approval/REC committee	- NHS Patients as source of tissue – HRA approval application (which includes a NHS REC review) to be made via IRAS. - Volunteers as source of tissue – Although may use UCL REC application **please recommend that an NHS REC application is made**. If the project is not NHS based a NHS REC review can be applied for without application for HRA approval. - Using tissue already collected under an existing ethics approval – check ethics and consent is valid. - As per the HTA code of practice to ensure transparency on areas of public concern, for example **where research is known or is likely to involve the commercial sector, genetic testing, samples being transferred abroad or the use of human tissue in animals**, these should be covered in the information used to support the consent process.
3. Check to see if a Materials Transfer Agreement is required *Guidance can be obtained from the Joint Research Office Contracts team*	**GOSH Patient tissue:** If GOSH patient tissue is to be transferred externally to another organisation (except to UCL-ICH) then a MTA may be required. **Commercial supplier**: Not usually required as conditions of tissue transfer form part of the terms

(for GOSH) and UCL Business (for UCL). *An MTA may not be required if this is covered by a research agreement or process detailed in a protocol approved by HRA/REC.*	of purchase. **Tissue Bank:** Not usually required as conditions of access to tissue forms part of application process to tissue bank. Some tissue banks however do require a MTA in place; please check if this is the case. **If Commercial company has made a request for clinical samples:** MTA would be required and there may be a cost chargeable to company for the samples. Please check that REC approval covers this and that there is appropriate consent in place
4. Update ReDA with details of the human tissue research study	Complete the human tissue information in the HTA tab of ReDA for the project being reviewed. Set a reminder in ReDA for 3 months before the end of the research study to forward the **Human Tissue Registration Form** to PI and/or research team for completion.
5. Issue R&D approval for research study (or confirmation of participation for HRA approval studies)	Issue a R&D approval letter (or confirmation of participation for HRA approval studies) to lead investigator o*nce the governance process has been completed*. For HRA approval studies a confirmation of site participation is issued. This letter/confirmation should include a reminder to the researcher of their legal responsibilities under the HTAct: Supply a copy of the R&D Office **Human Tissue Act Compliance form**.
Post Research	

6. Contact the lead investigator for information about plans for any human tissue still available at the end of the research study	Send the **Human Tissue registration form** to the lead investigator 3 months before the end of the research study - for completion and return to the R&D office.
7. Process the Human Tissue Registration Form	The information received should be processed and used to update all the appropriate fields in Reda (HTA tab). Further guidance on this is outlined in section 5.2 below. If the relevant material is to be used for further research then advise the researcher to apply for further REC approval before the end of the study. If a request is made to add tissue to GOSH/UCL-ICH holdings, the DI is to be informed and a meeting arranged to review documentation and provide a decision about declaration under the licence. It may not be possible to return tissue to the GOSH diagnostic archive however the R&D office can advise on this.

5.2. Post research management of Human Tissue

On completion of the study and hence expiry of the REC approval, the GOSH/UCL-ICH Human tissue licence will govern the storage of any residual	**Actions for Researchers**
	1. Apply to extend the HRA/REC approval to use the relevant material for further research.
	2. Transfer the relevant tissue into the holding of

relevant material. Researchers have these choices at this stage which are communicated to them in section 5.1 above: *Researchers should be aware of the implications of all these options when devising a consent procedure for the collection of relevant material: consent needs to be wide enough to allow continued storage of tissue for research purposes.*	UCL-ICH – with the permission of the DI. 3. Apply to set up a REC approved tissue bank by completing the IRAS form for new REC approval* and informing the GOSH/UCL-ICH DI. **** This cannot be done via an amendment to an existing REC approval on expiry of the original research project. Tissue banks do not fall under the remit of HRA approval.*** 4. Offer the tissue samples to other REC approved tissue bank(s). 5. Return the tissue to the relevant pathology/ diagnostic archive collection at GOSH. 6. Disposal of remaining tissue.

5.3. Post research management of Human Tissue

All those working with human tissue will require up to date training on the Human Tissue Act (every 3 years). Attendance on such training should be documented and available for inspection during audits and visits from the Human Tissue Authority.

The ICH Director and GOSH CEO have overall responsibility for ensuring the DI's and PD's have completed their training, this responsibility is delegated to the R&D office. The R&D office will ensure that appropriate training records are collected and stored.

When a research study involving Human Tissue is approved (or site confirmed if HRA approved) by the R&D office the PI is made aware of their responsibility to ensure all their

research team complete appropriate HTA training. It is the PIs responsibility for documenting this training accordingly.

Sources of training include:	
Face to face training	1. The R&D Governance team will provide training presentations on the Human Tissue Act. 2. Further requests for training can be made to the DI, PD's or the R&D Office.
Online training	3. The HRA or MRC online training on the Human Tissue Act is recommended to all UCL-ICH and GOSH staff who handle human tissue.

5.4. Audit

R&D auditing will concentrate on the review of project folders as part of quality assurance of the R&D review/approval process. There will also be opportunities for review of research studies to include review of research study site files which includes sample collection and transfer logs.

All human tissue samples related auditing will be conducted by appropriate Institute PD's on behalf of the UCL-ICH DI.

5. Related Documents

GOSH/ICH/FRM/R&D/004 Human Tissue Act Compliance

GOSH/ICH/FRM/R&D/005 Human Tissue Registration Form

6. References

UK Policy Framework for Health and Social Care
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

Human Tissue Act 2004
https://www.hta.gov.uk/policies/human-tissue-act-2004

HRA Codes and Practice and Standards
https://www.hta.gov.uk/hta-codes-practice-and-standards-0

The Human Tissue Authority website
www.hta.gov.uk/

NHS Research Ethics Committees online guidance
https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/research-ethics-committee-review/

HRA approval
https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/.