



Working with Human Tissue and Patient Information including a Checklist of Requirements and Responsibilities

Introduction

This checklist is designed to assist supervisors, research staff, newly appointed Principal Investigators and students not only to abide by the principles of the University’s Statement on Research Integrity but also to engage in a broader dialogue about research and the responsible conduct involving the use of human tissue in research. UCL’s Statement on Research Integrity and the UCL Code of Conduct can be found at the following links:

<https://www.ucl.ac.uk/research/integrity/integrity-at-ucl> AND
<https://www.ucl.ac.uk/governance-compliance/research-governance>.

These websites provide more detailed information about research conduct, research ethics, funding, conflicts of interest, authorship of manuscripts and conference proceedings, and how to acknowledge the source of human tissue. It is recommended that supervisors or personnel to whom this is delegated, discuss with research staff, newly appointed PIs and students the following issues and bring to their attention the checklist with recommended reading and training:

- What the University requires of its staff, students and visitors
- Relevant regulatory guidelines (HTA Standards for Research, HTA Codes of Practice)
- Project-specific requirements (e.g. human ethics approvals, risk of infection, material transfer agreements, disposal of samples etc.)
- Training available for staff, students and visitors

**It is advisable that visitors of longer than 3 months complete this training.

Please return the signed document along with your Training Certificates within two weeks of attending your safety induction to your local Biobank Manager and / or HTA Designated Individual

I have read and understand the information set out in the UCL document on Working with Human Tissue and Patient Information. I agree to abide by, and implement, all appropriate procedures as described in this document.

I understand that failure to follow this code could result in hazards to myself and my colleagues and that breaching these rules may lead to disciplinary action being taken.

- a) I am / am not* working with human tissue samples (including blood, blood products, tissue, urine, faeces etc) *Delete as appropriate
- b) I have / have not* attended UCL Occupational Health and Wellbeing and I am providing you with the outcome of my immunisation against Hepatitis B *Delete as appropriate
- c) I have not attended UCL Occupational Health and Wellbeing but I have provided the outcome of my immunisation against Hepatitis B from elsewhere (GP, travel clinic)
- d) I understand that where failure to respond to immunisation or circumstances which prevent vaccination, I must not work with human tissue until I have been advised by Occupational Health and Wellbeing Advisor if I can proceed in the absence of immunisation. I will be provided with written documentation from Occupational Health and Wellbeing.

NAME (print)

SignatureDATE

Supervisor / delegated signatory:



Name (print)

Signature.....DATE

Aspect of human tissue	Suggested action	Resources / Web Links	Initial / Date / Comments
<p>Introduction to Research using human tissue Human Tissue Authority</p>	<p>Discuss the remit of the HTA, the list of relevant material, exceptions and exemptions and when an HTA licence is required. Discuss the Codes of Practice and HTA Standards and how they relate to the project.</p> <p>Training to acquire knowledge of the human tissue act is mandatory if working with human tissue; training certificates must be provided to the HTA DI /PD, Head of Department or an appropriate individual to whom this task can be delegated, for example, tutor, course manager etc.</p>	<p>Link to the Human Tissue Authority https://www.hta.gov.uk/</p> <p>Link to HTA Codes of Practice and Standards for Professionals https://www.hta.gov.uk/guidance-professionals/codes-practice</p> <p>The MRC Regulatory Support Centre Learning Management System provides an e-learning course, 'Research and Human Tissue Legislation', at http://www.byglearning.co.uk/mrcsc-lms/course/, for which registration is required and assessments are available.</p>	
<p>Health and Safety when working with human tissue</p>	<p>All staff, students and visitors working with unfixed human tissue must be aware of the risk of being exposed to infectious agents, and the safety requirements that must be taken to reduce such a risk.</p> <p>Attend local safety induction attended: job hazard form completed; referral to Occupational Health and Wellbeing if required for Hep B vaccination / testing of immunity; local laboratory tour and provision of Personal Protection Equipment (lab coat, gloves, goggles etc).</p> <p>*Specifically vaccination against hepatitis B is required prior to working with unfixed human tissue</p>	<p>Link to UCL Health and Safety Policy https://www.ucl.ac.uk/safety-services/policies/2021/apr/health-and-safety-policy</p> <p>Link to Occupational Health and Wellbeing websites https://www.ucl.ac.uk/human-resources/health-wellbeing/staff-and-student-health and https://www.ucl.ac.uk/human-resources/health-wellbeing/workplace-health/faqs#About-OHW</p>	

Research Ethics	A discussion must take place around the ethical approval given for the research and a copy of the ethical approval should be provided / made accessible to those undertaking research. Anyone undertaking research must be listed on a delegation log, which is assigned to an ethics application approval.	Link to UCL Ethics http://ethics.grad.ucl.ac.uk/ Link to HRA ethical approval process http://www.hra.nhs.uk/ Link to JRO https://www.ucl.ac.uk/jro	
Information Governance	Discuss the concept of governance with respect to information relating to a person whose tissue is being used for research. Discuss the requirements for Information Governance training at UCL. Discuss the concept of data protection in relation to storage of participant information (patients and volunteers) and the logistics of storing this information.	Courses and online training in information governance are provided by SLMS at https://www.ucl.ac.uk/isd/itforslms/services/handling-sens-data/training-and-awareness . Link to UCL Information Governance and Data Protection https://www.ucl.ac.uk/human-tissue/information-governance	

	Awareness that access to patient information for research purposes is only permitted with patient consent.		
Transfer of human material and information	Awareness of the requirements of releasing tissue and data to other researchers within and external to the institution in which they work. Knowledge of when a material transfer agreement (MTA) is required.	Link to UCLB http://www.uclb.com/what-we-do/are-you-a-ucl-researcher/material-transfer-agreements .	
Biobanking at UCL	There are eight research tissue banks within UCL.	https://www.ucl.ac.uk/biobank	