

Human Tissue Research at UWE

3. The Human Tissue Records Management Manual

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1. Introduction to the Human Tissue Records Management Manual

The UWE *Human Tissue Research Records Management Manual* sets out expectations of the records that need to be kept by UWE Project Managers, by Laboratory Managers and by central Research Governance and Ethics teams, and by individual researchers working on Human Tissue projects in support of the Quality Management System.

2. Procedure for recording Human Tissue projects at UWE

a. The UWE Human Tissue Research Register

- i) The UWE Human Tissue Research Register is maintained by the Research Governance Officer. The format of the Register is illustrated in Appendix 1.
- iv) Projects are recorded in two sections of the Register: Projects that fall within the scope of the Human Tissue Act and projects that do not.
- v) All UWE Project Managers must register their project with the Research Governance Officer using the form detailed in Appendix 2 before they bring samples onto UWE premises. This will ensure that required ethical approvals are already in place.
- vi) The Register of projects that fall within the scope of the HT Act is presented to the Human Tissue Sub-Committee (HTSC) at every meeting and committee members can raise issues or concerns that they have with any project on the Register.
- vii) The Register is updated following the procedure in Section 2b. below.

b. Updates to the UWE Human Tissue Research Register

Projects that fall within the scope of the HT Act

- i) Updates to the Register of projects that fall within the scope of the HT Act are requested twice a year, in September and February, using the pro-forma in Appendix 3.
- ii) The Research Governance Officer requests updates, as the sole editor of the Register.

- iii) UWE Project Managers that do not respond to the request for updates will be reported to the HTSC at the next meeting and their Head of Department will be informed.
- iv) Outside of the twice yearly update, UWE Project Managers must inform the Research Governance Officer in a timely manner of any changes to their project (e.g. changes of staff or students working on the project, changes in collaborators, extension of project end date, substantial amendments to the NHS REC, changes in tissue being used).
- v) The Register is updated prior to each HTSC meeting, based on any updates received during that period (whether part of the twice yearly update procedure, or outside of this) and 'locked' for that period. The updated Register will then be presented at the next HTSC meeting for comment.
- vi) Members of the HTSC must notify the HTSC Officer no less than 5 working days in advance of a HTSC meeting if they wish to raise a query relating to a project on the Register.
- vii) If the query raised concerns a project that involves a member of the HTSC, they will be notified at the meeting by the Chair that a query has been raised, and asked to leave the room while the project in question is discussed. This ensures that all HT researchers (whether members of the HTSC or not) are treated equally when their projects are queried at committee meetings.
- viii) Following the HTSC meeting, a new version of the Register then becomes active until the next HTSC meeting. Updates will be requested again in line with the biannual procedure, and the process is repeated.
- ix) This mechanism allows a version of the Register to be 'locked' and archived following every HTSC meeting, which will support retrospective cross-referencing or querying if necessary.

Projects that fall outside of the scope of the HT Act

- i) All UWE Project Managers must register their project with the Research Governance Officer using the form detailed in Appendix 2 before they bring samples onto UWE premises. This will ensure that all necessary ethical approvals are already in place.
- ii) UWE Project Managers must inform the Research Governance Officer in a timely manner of any changes to their project (e.g. changes of staff or students working on the project, changes in collaborators, extension of project end date, substantial amendments to the NHS REC or changes in tissue being used).
- iii) Biannual updates will not be requested from UWE Project Managers for projects that fall outside of the scope of the HT Act.
- iv) The Register of projects that fall outside of the scope of the HT Act will not be presented at HTSC meetings.

- v) UWE Project Managers must inform the Research Governance Officer if their research changes in such a way that it falls within the scope of the HT Act.
- vi) UWE Project Managers will be included in communications to the UWE human tissue research community.
- vii) Notification of the end of a project – all projects
- viii) UWE Project Managers must inform the Research Governance Officer when a project has ended and confirm how any remaining samples will be dealt with, which must be in line with consents and permissions pertaining to those samples and the Human Tissue Act (e.g. transfer to a tissue bank, disposal, made the subject of a new NHS REC application). To support this process, the Research Governance Officer will contact UWE Project Managers eight weeks before the end date of their project to remind them of their responsibilities with regards to project samples.
- ix) Note: Tissue may be held for up to one year beyond the end date of the NHS REC approval for audit and data verification purposes only. Where a PI wishes to retain tissue for these purposes, a note to this effect must be made and a new end date entered on the UWE HT Register.
- x) Once a project has been completed it will be archived in the Register.
- xi) For projects that fall within the scope of the HT Act, once they are archived then updates will no longer be requested. The archived section of the Register is not presented to the HTSC.

3. Maintaining Project Level Information

The UWE Project Manager must maintain a project file detailing the following project information:

- UWE Human Tissue Registration Form
- Start and end date of the project.
- Ethics application and supporting documentation and favourable opinion and relevant associated correspondence, e.g. conditions 7 (may be NHS REC plus FREC/UREC ratification, or just FREC/UREC application). **Note:** we must have these even if we are not leading the ethical review.
- Any original applications to a research tissue bank.
- Permissions and conditions from a tissue bank and any amendments agreed.
- Approvals from NHS R&D Departments ('R&D' or 'Management' Approval), if required. **Note:** we must have these even if we are not leading the ethical review. Ethical approval may not be valid if tissue is obtained through an NHS organisation and appropriate R&D approvals are not in place. We would therefore be in breach of the Human Tissue Act.
- Research protocol
- Project funding application and approval, along with any conditions and

responses

- Contracts and agreements, including MTAs (these will also be held centrally, but researchers should have these to hand to refer to them during the project)
- Records of any amendments to the project (this may be major or minor amendments to NHS REC, ratified by FREC/UREC; amendments covered in annual reports, such as delays)
- Copies of annual reports and final reports submitted to the NHS REC
- Records of any arrangements agreed with collaborators (such as Steering or Advisory Committee papers and minutes, important email correspondence)
- All copies of UWE HT Research Quarterly Update Forms
- Records of the date received, storage location and disposal of any samples (e.g. UWE sample ledger)
- Records of names of UG and PG project students who will be working on research projects involving relevant material

Project Personnel records to be held by UWE Project Manager on Project File

- Records of all staff members working on the project with dates
- For staff, where applicable, evidence of relevant HT related competence, such as evidence of training completed (e.g. MRC e-Learning module on Research and Human Tissue legislation assessment)
- Records of all students working/who have worked on the project, with dates
- For students, evidence of HT related training completed

4. Managing and recording the locations where Human Tissue samples are stored at UWE

c. Individual Samples

- i) Human tissue samples must be clearly labelled and easily identifiable by a third party. This must always be done.
- ii) Whenever possible, an individual sample must be labelled with a unique identifier, which makes it identifiable from the Sample Ledger for that project (see Section 4c. on Sample Ledgers below).
- iii) The UWE Project Manager must define an identification system appropriate to the project needs, but that meets the requirements of i) and ii) above.
- iv) Where it is not physically feasible to label individual samples (e.g. containers of pooled urine), then the sample(s) storage container must be labelled with a unique identifier, which makes it identifiable on the Human Tissue Sample Location Notice for that storage area (see Section 4b. on Human Tissue Sample Location Notices below).

d. Locations where HT samples are stored

- i) Human tissue samples must be stored in an identifiable, secure storage area (e.g. a cupboard or cabinet, or a fridge or freezer within a secure laboratory or room). Human tissue must only be stored in this area. Shelves, drawers or bins within the storage area must be labelled with a unique identifier which can be used to identify a sample's storage location on the 'Human Tissue Sample Location Notice' (see iii below) and the project 'human tissue (HT) sample ledger'
- ii) We would recommend that all human tissue samples are stored within a secure laboratory.
- iii) If samples are stored within a shared laboratory then the Laboratory Manager* (where present) must designate a secure location where human tissue samples can be stored and assign a unique identifier to that storage location.
- iv) The Laboratory Manager* will manage access to the designated human tissue storage area, and have a procedure for allocating space to researchers.
- v) A 'Human Tissue Sample Location Notice' must be clearly displayed on the front of each fridge/freezer/cupboard containing human tissue samples. See Appendix 4 for examples.
- vi) The 'Human Tissue Sample Location Notice' must clearly identify which location it refers to using the unique identifier assigned in iii) above. For example 'Room 3X35, Freezer 3, shelf 4, box 7'
- vii) The notice must detail for each 'identifiable location' within the Freezer / cupboard:
 - viii) Project ID/Name
 - ix) UWE Project Manager name
 - x) NHS REC Reference Number
 - xi) Start date of NHS REC approval
 - xii) End date of NHS REC approval
 - xiii) UWE FREC / UREC Reference Number
 - xiv) An example is given in Appendix 4.
- xv) All HT Sample Location Notices that apply to a specific laboratory must be held in hard copy in a file easily accessible within that laboratory. The file should be maintained by the Laboratory Manager*
- xvi) An electronic copy of all HT Sample Location Notices that apply to a specific laboratory must also be held on the central S:drive. These files should be maintained by the Laboratory Manager³.
- xvii) Storage locations will be audited according to their HT Sample Location Notices by the Laboratory Manager on a regular basis.

³ *Where a laboratory area is not overseen by a laboratory manager, the laboratory manager responsibilities will fall to the UWE Project Manager.

xviii) If samples are removed (e.g. for analytical work), then they should be returned to their designated storage location as soon as possible.

e. Sample Ledgers

- i) Where it is possible to label individual samples, then a 'Sample Ledger' must be held for each project, according to the format in Appendix 5.
- ii) This must be maintained by the researchers on the project, and it is the responsibility of the UWE Project Manager to ensure that sample ledgers are established and kept up to date.
- iii) The ledger must be updated each time a new sample is brought onto UWE premises, and each time a sample is transported off-site, rendered acellular or disposed of.
- iv) An electronic version of the sample ledger must be saved on a central UWE server within a week of any updates being made. This is crucial in demonstrating compliance with the HT Act where tissues are being held on UWE premises 'incidental to transport' and so must be transported on or rendered acellular within a week.
- v) The sample ledger should record:
 - Project title
 - Uwe Project Manager and Lead Worker
 - NHS REC Reference numberThen for each sample:
 - Sample ID
 - Date received
 - Sample description
 - Source
 - Storage Location. **Note:** this must be specific enough to allow the sample to be identified/located by a third party, e.g. the laboratory manager.
 - Date used / destroyed / returned
 - Method of disposal
- ii) Sample ledgers may be called in for audit at any time by the Human Tissue Sub-Committee or by the Laboratory Manager on behalf of the Human Tissue Sub-Committee and so must be kept up to date. Copies of Sample Ledgers **will** be called in by the Research Governance Office twice per year along with routine requests for Human Tissue Register updates.

5. Contact for further details

For further information and guidance on conducting research using human tissue at UWE, please contact the Officer of the Human Tissue Sub-Committee:
researchgovernance@uwe.ac.uk

Document Owner: Ros Rouse (Research Governance Manager)

Appendix 1 - Format of the UWE Human Tissue (Relevant Material) Research Register

No	Date form received	Name of UWE Project Manager	Name of Students (any level)	Name of Collaborators (UWE and External)	Title of project	Type of relevant material being used in the study	NHS Ref No	Sponsor	Start date	End date	Expiry date for use of stored samples	UREC / FREC ref no	Date of registration	NHS REC application on file?	NHS REC approval letter on file?	Other supporting docs on file?	Actions
Projects using 'Relevant Material'																	
1	01/12/12	John Smith	Joanna Smith (UWE)	None	Human Tissue Research Project Example Title	Whole Blood Samples	12/SW /0000	UWE	01/01/13	31/01/15	31/01/15	HLS-XX-XXX	14/12/12	Yes	Yes	Yes	None
Archive of completed projects																	
3	01/12/11	John Smith	Joanna Smith (UWE)	None	Human Tissue Research Project Example Title	Whole Blood Samples	11/SW /0000	UWE	01/01/12	31/12/14	31/12/14	HLS-XX-XXX	10/12/11	Yes	Yes	Yes	None. UWE PM confirmed that all samples disposed of (31/12/14)

Appendix 2

UWE Human Tissue Research Registration Form

Name of Applicant⁴:		
Job Title & Department:		
Title of the Project:		
Name of <u>all</u> students (at any level) working on the project. Please indicate level (e.g. PhD / MSc / BSc):		
Name of <u>all</u> UWE members of staff working on the project:		
Name of all external Principal Investigators working on the project:		
Institution acting as Sponsor⁵ for the Project:		
Type of human tissue being used in the study:		
Is the tissue considered to be 'Relevant Material' under the HT Act⁶ for the purposes of this research project?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If 'No', please confirm the reason for this.		
Start Date of Project:	End Date of Project:	
Expiry Date for use of stored samples (if different from End Date):		
For projects involving 'Relevant Material' and / or the NHS please provide:	the NHS REC Reference Number⁷:	UWE FREC / UREC Reference Number⁸:
For 'Non-relevant Material' please provide the UWE FREC / UREC Reference Number:		
HAS Faculty Only* HAS Research Governance Record Reference Number:		
Date of Application:		
Signed by:	Print Name:	

⁴ This should be the UWE Project Manager as defined in the Code of Good Research Conduct (www1.uwe.ac.uk/research/researchgovernance). For PhD Students this should be the Director of Studies.

⁵ Project Sponsor as defined under the Department of Health Research Governance Framework (www.hra.nhs.uk/resources/before-you-apply/roles-and-responsibilities/sponsor/).

⁶ Further details of the Human Tissue Act (2004) and the list of materials considered to be 'relevant materials' under the Act can be found at: <https://www.hta.gov.uk/policies/list-materials-considered-be-%E2%80%98relevant-material%E2%80%99-under-human-tissue-act-2004>.

⁷ This will be either the project-specific NHS REC Reference Number, or the Tissue Bank's NHS REC Reference Number if samples are to be sourced from a Tissue Bank.

⁸ All external REC approvals must be 'ratified' by a UWE REC before samples can be brought onto UWE premises.

Note: Please ensure that you complete the checklist overleaf before submitting this form. Projects will not be registered unless the checklist is completed.

Note: Please ensure that you do not bring any human tissue samples onto UWE premises until you have received your UWE Human Tissue Register Reference Number from the HTSC Officer.

Please send all completed forms to the HTSC Officer researchgovernance@uwe.ac.uk.

CHECKLIST	Please check if relevant
<p><u>'Relevant Material':</u></p> <p>Has a copy of the project specific NHS REC Application Form and Approval Letter or Tissue Bank Application Form and Approval Letter / Material Transfer Agreement been submitted to the appropriate UWE Research Ethics Committee (UREC or FREC)?</p> <p>If the project involves an NHS Trust, has evidence of HRA or Trust R&D Approval been submitted to the UWE Research Ethics Committee?</p> <p>Has the UWE Research Ethics Committee 'ratified' the approval for this project and do you have a Reference Number?</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>
<p><u>'Non-relevant Material' (involving the NHS):</u></p> <p>Has a copy of the project specific NHS REC Application Form and Approval Letter been submitted to the appropriate UWE Research Ethics Committee (UREC or FREC)?</p> <p>Has evidence of HRA or Trust R&D Approval been submitted to the UWE Research Ethics Committee?</p> <p>Has the UWE Research Ethics Committee 'ratified' the approval for this project and do you have a Reference Number?</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p> <p><input type="checkbox"/></p>
<p><u>'Non-relevant Material' (not involving the NHS):</u></p> <p>Has a UWE Human Tissue Ethics Application Form been submitted to the appropriate UWE Research Ethics Committee (UREC or FREC), or evidence of ethical review by an external REC been submitted if the project is not being led by UWE?</p> <p>Has the UWE Research Ethics Committee given approval for this project and do you have a Reference Number?</p>	<p><input type="checkbox"/></p> <p><input type="checkbox"/></p>
<p>Have you the read the UWE Human Tissue Operating Procedures?</p>	<p><input type="checkbox"/></p>
<p>Have you read the UWE Human Tissue Records Management Manual and SOPs?</p>	<p><input type="checkbox"/></p>
<p>Have you notified appropriate staff (e.g. the Laboratory Manager) of your intention to bring human tissue samples onto UWE premises?</p>	<p><input type="checkbox"/></p>
<p>Have you set up a Project File and a ledger to record the collection, storage and disposal of human tissue samples (as per the Records Management Manual)?</p>	<p><input type="checkbox"/></p>

To be completed by the Research Governance Officer

Date received by the Research Governance Officer:	
UWE Human Tissue Register Reference Number:	

Appendix 3

EXAMPLE UWE Human Tissue Research Update – March 2015

UWE Project Manager: Prof Jane Doe

Register Ref No.	Name of UWE Project Manager	Name of students (at any level, please specify level for each name)	Name of collaborators (UWE and external)	Project Title	Type of relevant material /acellular material being used in the study	NHS REC Ref Number	Sponsor	Start Date	End Date	UWE UREC / FREC Ref Number
100A	Prof Jane Doe	Jane Smith (PhD) John Doe (BSc)	Dr John Smith (North Bristol Trust)	Cancer biomarkers project with North Bristol Trust	Blood samples from cancer patients held at North Bristol Trust	15/SW/99 99	UWE	01/04/15	31/12/15	HAS/15/03/99
200E	Prof Jane Doe	Alice Doe (BSc)	None	Breath samples project with UWE students (healthy volunteers)	Breath Samples (not relevant material)	N/A	N/A	01/04/15	31/12/15	N/A (low risk)

Action:

- Confirm that the details given above are correct, and inform HTSC Officer (researchgovernance@uwe.ac.uk) if any changes need to be made to the record.

Many thanks.

iii)

Unregistered samples / projects

**** ACTION REQUIRED:**

Please check here to confirm that you are not holding any other materials at UWE considered to be 'relevant materials' under the Human Tissue Act 2004.

If you have any other projects not registered on the Human Tissue Register (i.e. in addition to the projects listed above; either utilising the samples referred to in the projects listed above, or utilising new samples) please provide full details in the format given above.

**** NEW** Student Projects:**

Please provide full details in the format given above of **all student projects** (including undergraduate projects) that you are currently supervising that involve human tissue.

Please check here to confirm that the human tissue research work being undertaken by any students that you are supervising within this quarter falls entirely within an existing NHS REC ethics approval (or UWE UREC / FREC approval if using acellular material).

Many thanks.

Please be aware that all research at UWE that involves Human Tissue must be registered on the UWE Human Tissue Register.

**For further information please refer to the UWE Ethics webpages:
www1.uwe.ac.uk/research/researchethics/policyandprocedures.aspx**

If you have any questions or queries about this form, do not hesitate to contact the Human Tissue Sub-Committee Officer:

researchgovernance@uwe.ac.uk or Ext. 81644

Appendix 4

UWE Recommended HT Sample Location Notice

-80 freezer inventory (2G17)

Comark I.D: 2G17-80 freezer.

Transmitter: CE05100190

- **Please use your allocated space only.** If you do not have allocated space, please contact The Laboratory Manager in 2GXXa. (Ext. 88888)
- Clearly label all samples with your name, contents and the date the samples were frozen (freezer/sample boxes are available from the cupboard in 2G6).
- If you need additional space, contact the Laboratory Manager. **Samples which are unlabelled or found in unallocated storage bins/racks will be disposed of.**

The inventory below reflects the physical layout & position of the bins and racks in the freezer from top to bottom shelf.

Bin 1 Jane Doe	Bin 2 John Smith	Bin 3 Jane Smith	Bin 4 Jane Smith
Bin 5 Reserve! Ask Laboratory Manager before storing anything in this space	Bin 6 NHS REC N°: 00/H000/00 Example Human Tissue Project Title A UWE PM: John Smith Project start: 22/7/2012 Project end: 22/9/2017 NHS REC N°: 00/H000/XX Example Human Tissue Project Title B UWE PM: John Smith Project start: 01/02/15 Project end: 31/01/18	Bin 7 John Doe	Bin 8 John Doe
Bin 9 Reserve! Ask Laboratory Manager before storing anything in this space	Bin 10 Dry ice	Bin 11 Reserved for Laboratory Manager	Bin 12 John Doe
Bin 13 NHS REC N°: 00/H000/BB Example Human Tissue Project Title C UWE PM: Jane Doe Project start: 01/10/2014 Project end: 01/10/2016 NHS REC N°: 00/H000/YY Example Human Tissue Project Title D	Bin 14 Reserve! Ask Laboratory Manager before storing anything in this space	Rack 1 Reserve! Ask Laboratory Manager before storing anything in this space	Rack 2 John Doe

UWE PM: Jane Doe Project start: 01/07/15 Project end: 31/07/16			
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Last audit: 14th May 2015

Laboratory manager: XXXXXX

Appendix 5

UWE Recommended Sample Ledger

Human tissue (relevant material) storage ledger.					
Project title:	Human Tissue Project				¹ Sample ID should be anonymised if required. Must not contain any information which identifies the donor.
Principal Investigator:	Jane Smith				² State the type of sample/relevant material.
Lead Worker:	John Smith				³ Locations must be specific enough to allow identification of the sample (e.g. lab, freezer, rack/shelf, box number & sample number).
LRES/NRES number (if applicable)	08/H0XXX/100				⁴ Samples of relevant material acquired for research purposes must be recorded on the form within 5 days of receipt.
Sample ID ¹	Date received	Sample Description ²	Source	Storage location ³	Prepared by (initials)
TBES01XX	26/06/2014	HUMAN TONSILS (PAIR)	BIIRTB (BRISTOL TISSUE BANK)	2K6 incubator	
TBES02XX	27/06/014	HUMAN TONSILS (PAIR)	BIIRTB (BRISTOL TISSUE BANK)	2K6 incubator	
TBES03XX	02/07/2014	HUMAN TONSILS (PAIR)	BIIRTB (BRISTOL TISSUE BANK)	2K6 incubator	
TBES04XX	02/07/2014	HUMAN TONSILS (PAIR)	BIIRTB (BRISTOL TISSUE BANK)	2K6 incubator	
TBES05XX	24/07/2014	HUMAN TONSILS (single)	BIIRTB (BRISTOL TISSUE BANK)	2K6 incubator	
TBES06XX	24/07/2014	HUMAN TONSILS (single)	BIIRTB (BRISTOL TISSUE BANK)	2K6 incubator	