Human Tissue Research at UWE

2. Operating Procedures and Guidance for Staff and Students

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Contents

NB: This guide does not cover the use of tissue in teaching or public display. These will be the subject of separate guidance.

Key Messages

- Ethical review is always necessary for human tissue research
- All research at UWE that involves human tissue (relevant or non-relevant materials) must be registered on the UWE Human Tissue Research Register
- The UWE Project Manager is responsible for the good conduct of their human tissue research project
- The consequences of poor practice are significant and could include a breach of the Human Tissue Act, and/or be considered 'Research Misconduct'
- If you have queries about human tissue research at UWE then contact the UWE Human Tissue Sub-Committee via the Research Governance Team (researchgovernance@uwe.ac.uk).
- If you have concerns about the conduct of a human tissue research project at UWE then contact the Chair and Officer of the UWE Human Tissue Sub-Committee via the Research Governance Team (researchgovernance@uwe.ac.uk).
- Further information can be obtained from the UWE Human Tissue Research webpages http://www1.uwe.ac.uk/research/researchgovernance/resourcesforresearchers/humantissueresearch.aspx
- The definitions used throughout this document are set out in **Annex 1**.

UWE does not currently hold an HTA licence for storage of human tissue for research purposes (as defined by the Human Tissue Act). This means the licensable storage of relevant material for research at UWE must be covered by a valid, in date, NHS Research Ethics Committee (NHS REC) favourable opinion for a specific research project, or covered by the NHS REC approval of a Research Tissue Bank, prior to human tissue being brought on to UWE premises.

1. Introduction

This document sets out the University's operating procedures related to the ethical review, oversight and management of Human Tissue Research. The University is committed to high quality research and to promoting high standards of scientific conduct and research practice. The University has recently approved a *Code of Good Research Conduct* (http://www1.uwe.ac.uk/research/researchgovernance/codeofgoodresearchconduct.aspx), in the context of the *Concordat to Support Research Integrity* (UUK 2012), which sets out the University's responsibilities, requirements and expectations in relation to good research practice. The University, and its researchers, must be compliant with the law, and research must be ethical and of the highest scientific quality.

2. Scope

This is not a guide covering all aspects of the Human Tissue Act as it relates to Human Tissue Research. Researchers working on human tissue are expected to familiarise themselves with the requirements placed upon them by legislation and regulation, whether or not those requirements are specifically covered in these operating procedures. Researchers are also required by the University to follow best practice, as set out in the Codes of Practice produced by the Human Tissue Authority (HTA) (https://www.hta.gov.uk/) and should fully familiarise themselves with the advice available in relation to their research area on the HTA website. These guidelines are intended to highlight to researchers the issues about which they should be informed before working with human tissue, and set out the University's expectations and procedures in key areas. It is the responsibility of the UWE Project Manager to understand and be familiar with the requirements of the HTA, and ensure that these are complied with. This guidance draws heavily on advice available from the HTA website.

Further guidance is available from, and all queries to the Human Tissue Authority must be routed through, the UWE Human Tissue Sub-Committee (HTSC) via the Committee Officer (researchgovernance@uwe.ac.uk).

3. Expectations of UWE Researchers

3.1 UWE requires all human tissue researchers working at, or under the auspices of, UWE to comply with the provisions set out in these operating procedures, and in the *UWE Code of Good Research Conduct*. At all times researchers must make

themselves aware of, and ensure that they are operating within, the law and regulation, according to sound ethical practice, and in line with the provisions of the HTA Codes of Practice.

3.2 UWE expects all human tissue researchers working at, or under the auspices of, UWE to have completed the following online human tissue training provided by the Medical Research Centre (MRC) Regulatory Support Centre at: www.byglearning.co.uk/mrcrsc-lms/course/category.php?id=1

The MRC Data and Tissues Toolkit: http://www.dt-toolkit.ac.uk/home.cfm is also a useful resource.

The MRC human tissue legislation summaries are also a useful resource, although as these are summaries, researchers should always make themselves aware of the full detail in areas of relevance: www.mrc.ac.uk/research/facilities/regulatory-support-centre/human-tissue/.

3.3 UWE will provide guidance for researchers. Human tissue regulation and ethics is not always straightforward, and the Human Tissue Sub-Committee will provide guidance on request, via the HTSC Officer: researchgovernance@uwe.ac.uk.

4. What is Good Practice in Human Tissue Research?

All researchers at UWE should familiarise themselves with the UWE *Code of Good Research Conduct* (http://www1.uwe.ac.uk/research/researchgovernance/codeofgoodresearchconduct.aspx).

The Human Tissue Act includes provisions for Codes of Practice to be made by the HTA on a number of issues. The Codes form part of the regulatory system under the Human Tissue Act. Their purpose is to provide guidance to persons carrying out activities within the HTA's remit and to lay down the standards expected in the carrying out of such activities. The Codes provide detailed advice on the matters that they cover and include an explanation of requirements under the Human Tissue Act and the Regulations.

The Codes of Practice have been divided into seven documents available to download from the HTA website at:
https://www.hta.gov.uk/hta-codes-practice-and-standards-

Of the seven Codes of Practice, those of most relevance to the work carried out at UWE are:

- Code A: Guiding Principles and the fundamental principle of consent
- Code E: Research Standards and guidance

UWE requires all researchers using human tissue to familiarise themselves with, and always comply with, the relevant Codes of Practice.

5. Governance and Formal Communication

5.1 Governance of Human Tissue Research and teaching at UWE

The Human Tissue Sub-Committee (HTSC) of the University Research and Knowledge Exchange Committee (URKE) is responsible for the oversight of the use of human tissue for research and teaching at the University. The Committee will oversee the *UWE Human Tissue Research Register* (further information about the Register is given in Section 14 below), and in turn will report annually to the URKE. The Committee will also raise formally with Deans any breaches of compliance or research governance which have come to the Committee's attention, and report any serious concerns to the URKE in a timely way. The Committee will identify good practice, and monitor good governance. The Committee will offer guidance to UWE researchers in relation to the use of human tissue. The Committee may be contacted via the Officer. Any communications with the Human Tissue Authority must be made via the HTSC. The terms of reference of the HTSC are attached at **Annex 2**.

5.2 Serious Concerns

If a UWE staff member or student has a serious concern relating to the use of human tissue at UWE or by UWE researchers, this should be raised with the HTSC Officer and Chair. However, if there is an urgent issue of safety (including health and safety or safeguarding concerns) in any way, this should be raised by the appropriate Faculty and University mechanisms, in addition to informing the HTSC Officer and Chair.

5.3 Routine Communications

The HTSC will routinely communicate with Faculties via the Dean, Associate Deans, Heads of Department and Associate Heads of Department, as appropriate. Communications, including guidance, will also be sent where appropriate to

researchers sourced from the *UWE Human Tissue Research Register*.

5.4 Informal Communications

Researchers wishing to seek guidance from, or raise issues with, the HTSC should do so via the Officer who will, where appropriate, facilitate an informal discussion with the most appropriate HTSC member.

6. What is the Human Tissue Act?

6.1 The Human Tissue Act 2004 covers England, Wales and Northern Ireland. The Human Tissue Authority (HTA) was established by the Act to regulate activities concerning the removal, storage, use and disposal of human tissue. The Act makes consent the fundamental principle underpinning the lawful storage and use of body parts, organs and tissue from the living or the deceased for specified purposes. Further information on Consent can be found in Section 8 below.
The key points of the Human Tissue Act 2004 (taken from the HTA website), are:

- The Human Tissue Act 2004 regulates the removal, storage and use of human tissue. This is defined as material that has come from a human body and consists of, or includes, human cells.
- The Human Tissue Act 2004 creates a new offence of DNA 'theft'. It is unlawful to have human tissue with the intention of its DNA being analysed, without the consent of the person from whom the tissue came.
- The Human Tissue Act 2004 makes it lawful to take minimum steps to preserve the organs of a deceased person for use in transplantation while steps are taken to determine the wishes of the deceased, or, in the absence of their known wishes, obtaining consent from someone in a qualifying relationship.

Offences under the Human Tissue Act 2004 (taken from the HTA website) are:

- Removing, storing or using human tissue for Scheduled Purposes without appropriate consent.
- Storing or using human tissue donated for a Scheduled Purpose for another purpose.
- Trafficking in human tissue for transplantation purposes.
- Carrying out licensable activities without holding a license from the HTA (with lower penalties for related lesser offences such as failing to produce records or obstructing the HTA in carrying out its power or responsibilities).
- Having human tissue, including hair, nail, and gametes (i.e. cells connected with sexual reproduction), with the intention of its DNA being analysed without the consent of the person from whom the tissue came or the consent

of those close to them if they have died. (Medical diagnosis and treatment, criminal investigations, etc., are excluded).

Human tissue research in Scotland is governed by the Human Tissue (Scotland) Act 2006. The first four offences only apply in England, Wales and Northern Ireland, although the Human Tissue (Scotland) Act 2006 has similar offences and penalties. The offence of DNA theft applies UK-wide. The Human Transplantation (Wales) Act 2003 amended the Human Tissue Act 2004 to allow for consent to deceased organ donation to be deemed in certain circumstances when a person both lived and died in Wales; however UWE requires NREC approval and for the tissue to come from the living.

6.2 The Human Tissue Act is regulated by the HTA, which issues licences for the storage and use of human tissue, carries out inspections on licensed premises and promotes good practice on all aspects of the handling, use, storage and disposal of human tissue.

6.3 Research using human embryos and gametes is not covered by the Human Tissue Act. The Human Fertilisation Embryology Authority (HFEA) regulates research using human embryos and gametes (www.hfea.gov.uk). UWE Researchers wishing to use embryos or gametes are required to familiarise themselves with the guidance on the HFEA web site, and seek guidance from the HTSC (via the Officer) at the outset.

7. What is human tissue and what is relevant material?

7.1 Human tissue defined as relevant material under the Human Tissue Act

7.1.1 The Human Tissue Act defines human tissue as 'material that has come from a human body and consists of or includes human cells' and is frequently referred to in the Act as 'relevant material'. The Act defines relevant material as human tissue, other than gametes, which consists of, or includes cells. Relevant material does not include embryos outside the human body, or hair and nail from the body of a living person. Only relevant material is covered by the Human Tissue Act.

The HTA website gives a number of examples of types of relevant material: List of materials considered to be 'relevant material' under the Human Tissue Act 2004. (The current list is also included at **Annex 3**).

Examples of human tissue that have been used for research at UWE include blood, brain cells, bone marrow, peripheral blood monocytic cells (PBMCs), histological sections, mesenchymal stem cells, urine, faeces and saliva.

i) Specifically identified relevant material

This includes material such as bodies, organs and tissues, consisting largely or entirely of cells, and clearly identifiable.

ii) Processed material

Where a processed material is generally agreed – as a result of the process – to leave it always either cellular or acellular, then the presumption should be that all examples should be regarded as such. The HTA would rely on an assurance that the process in question had been carried out. Under this category, plastinated tissue and plastinated body parts (where the cellular structure is retained by the plastination process) are considered relevant material; while plasma or serum, for example, will not be regarded as such. Plasma and serum, widely produced from blood taken for diagnostic investigations, are however examples of where 'normal expectations' may well need to be applied. There is more information on this in the HTA's List of materials considered to be 'relevant material' under the Human Tissue Act 2004. If there is any uncertainty about whether a given process renders tissue acellular, then guidance must be sought from the HTSC (via the Officer).

iii) Bodily waste products (including excretions and secretions)

The HTA states that bodily waste should normally be regarded as relevant material. The Act's wording is clear and reflects the possibility that even a single cell can be subject to an activity such as research. There will be cases where a researcher believes that material, intended for a scheduled purpose, is actually acellular. In such cases, where there is still uncertainty after HTSC consideration, the University may decide to approach the HTA for advice.

As set out at Section 6.3 above, embryos and gametes are regulated by the HFEA, therefore bodily products such as semen are not covered by the HTA but must comply with HFEA regulation.

iv) Cell deposits and tissue sections on microscope slides

In general, cell deposits or tissue sections on microscope slides are considered to constitute relevant material. This is because such deposits or sections are likely to contain whole cells or are intended to be representative of whole cells.

v) DNA

The Human Tissue Act 2004 creates a new offence of DNA 'theft'. It is unlawful to have bodily material with the intention of its DNA being analysed, without the consent of the person from whom the tissue came. 'Bodily material' differs from

'relevant material' as it includes hair and nails from the living as well as the deceased. It also includes gametes (human sperm and eggs). As the DNA itself (in contrast to the bodily material from which it originated) is not considered to be relevant material by the HTA, it can be stored without a licence.

The results of DNA analysis can be used for research without consent (although the HTA recommends consent is sought where practical to do so), providing all three of the following conditions are met:
a) the bodily material from which the DNA is extracted is from a living person;
b) the researcher is not in possession, and not likely to come into possession of information that identifies the person from whom it has come
c) the material is used for a specific research project which has received ethical approval from a recognised REC.

Example
A researcher is using the results of DNA analysis extracted from tissue biopsies from living people as part of a research project that has been approved by a recognised REC (e.g. NREC or FREC/UREC). The researcher will not come into possession of any patient identifiable information. No offence will be committed if consent is not obtained.

The DNA analysis offence in the HT Act applies only to bodily material; however, it is possible to extract human DNA from acellular materials, such as serum, for analysis. The ethical issues in the use of this material are the same as for those using bodily material and, therefore, the Health Research Authority (HRA) and the Devolved Administrations expect researchers intending to extract human DNA from acellular material for research analysis to submit their proposals for ethical review by a recognised REC (e.g. NREC or FREC/UREC). These principles also apply to RNA analysis if it is to be used to provide information about DNA.

The MRC Regulatory Support Centre also has a Guidance note on DNA Analysis: www.mrc.ac.uk/research/facilities/regulatory-support-centre/human-tissue/. Where consent is in place for DNA analysis, no requirement for NHS REC approval would arise. In some cases consent is only given to analyse the DNA for the specific study – in these circumstances, further ethical approval would need to be sought to analyse DNA in further projects. Researchers may anticipate this by seeking broad consent at the outset.

Under NHS research governance systems, NHS REC approval is not required for research involving anonymised extracted DNA, as the research involves neither tissue (i.e. cellular material) nor data of NHS patients. NHS REC approval would only be required where identifying data is held with the DNA sample. Further information on research with DNA can be found from the Health Research Authority (HRA) website:

www.hra.nhs.uk/resources/research-legislation-and-governance/questions-and-answers-the-human-tissue-act-2004/.

Note: approval from a UWE Research Ethics Committee will **always be needed for DNA research**, whether NHS REC approval is required or not.

7.2 Definition of Research

There is another crucial element in relation to whether collection, storage and use of human tissue comes under the provision of the Human Tissue Act, and that is whether it falls under the definition of research (as defined by the Act at point vi below), or it is for another scheduled purpose.

Research is one of a number of scheduled purposes under the Act. The full list of scheduled purposes (taken from www.legislation.gov.uk/ukpga/2004/30/schedule/1) is included below:

i) Anatomical examination.
ii) Determining the cause of death.
iii) Establishing after a person's death the efficacy of any drug or other treatment administered to him.
iv) Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person).
v) Public display.
vi) Research in connection with disorders, or the functioning, of the human body.
vii) Transplantation

7.3 Licensing Exceptions

There are a number of 'licensing exemptions' under the Human Tissue Act, which means that in some cases it is not necessary to have a human tissue licence in order to store human tissue. These are set out in detail at: www.hta.gov.uk/policies/licensing-exemptions and discussed further in Section 9 below.

7.4 UWE Requirements in relation to Exceptions

What this means in practice is that there are occasions where human tissue may be held at UWE for research without falling under the ambit of the Human Tissue Act. The most likely scenarios for researchers at UWE include:

i) Where (the activity) research does not fall within the definition of research above, i.e. where it is not 'research in connection with disorders, or the functioning of, the human body'. It is not always easy to determine whether the kind of research being

proposed falls within the definition of the Act. In cases where it is considered that the proposed research may not fall within the definition, and therefore not be covered by the Act, guidance should be sought from the HTSC, via the Officer.

ii) Where storage of tissue is incidental to transportation, see Section 9.1 below.

iii) Where human tissue material is not cellular, see Section 9.4 below.

Because it is a matter of legal compliance, UWE requires absolute certainty in relation to whether human tissue does or does not fall within the Act. The University also regards human tissue, cellular or otherwise, to be a valuable resource which must be treated with respect. The University therefore requires that:

a) All research at or under the auspices of the University involving human tissue should go through ethical review and have appropriate ethical approval. Usually this will require approval from an NHS REC because such approval constitutes one of the licence exemptions referred to above. A research project which does not fall within the provisions of the Human Tissue Act (because it is not collecting or using 'relevant material' or does not fall within the definition of research within the Human Tissue Act as set out above) and therefore does not need NHS REC approval to permit storage at UWE still needs UWE ethical review if it involves human subjects or the collection and/or use of human tissue (including for example hair, urine, fingerprints, DNA). See Section 11 below for more information about ethical review.

b) All research, whether using cellular tissue for a scheduled purpose, using cellular tissue for an unscheduled purpose, or human tissue which is acellular must be registered on the *UWE Human Tissue Research Register*. As well as enabling the University to hold a record of human tissue use on its premises, this enables the HTSC to communicate with all researchers using human tissue of any kind for any purpose at UWE. It is recognised that researchers may move between using relevant and non-relevant material over time, and it is therefore considered important that HTSC communications go to all who may be involved, to ensure all researchers are equally supported. Further information about the Register is given in Section 14 below.

Any researcher wishing to bring human tissue on to UWE premises must first notify and seek guidance from the HTSC via the Officer. This will usually be a relatively simple 'check' as to whether the tissue falls within the Act, but where there is doubt, it may be necessary for the University to seek advice from the HTA. Researchers should also be aware that as their programme of research evolves over time, that may bring it within the scope of the Human Tissue Act, and should be alert to this issue and take appropriate action including seeking advice from the HTSC.

8. Consent

8.1. Lawful storage and use of relevant material

The Human Tissue Act makes consent the fundamental principle underpinning the lawful storage and use of relevant material. Consent must be sought for the removal, storage and use of human tissue for certain scheduled purposes, including research in connection with the functioning, or disorders, of the human body. The diagram overleaf illustrates the link between ethical approval and the licencing and consent exceptions of the Human Tissue Act. It is essential that the person giving consent understands the nature and purpose of what is being proposed, to enable them to make a fully informed decision. This should include the way in which the tissue will be used, as well as any potential risks in the way the sample will be obtained and used.

Where the relevant material is from a living person, but the researcher cannot come into possession of information which identifies the persons donating the material ***and*** **where the material is to be used for a specific research project approved by a recognised research ethics committee** (i.e. an NHS REC), **specific** consent is not required. Researchers should note that material sourced under the above conditions **can only be used for the particular research project for which it was obtained.** At the end of the project, the material must either be disposed of, moved to a licensed facility (if permitted by consent) or further NHS REC project favourable opinion obtained, provided consent is in place for further use. Please note: this is the only circumstance in which consent is not needed – researchers must contact the HTSC Officer (researchgovernance@uwe.ac.uk) for such a project.

Example
A researcher wishes to use paraffin-embedded blocks of surgically removed thyroid tissue stored in the archives of a pathology department after its use for diagnosis. As consent for the use of their tissue for research was not originally sought from the patient, it can only be released from the diagnostic archive if it does not identify the patient and is used in a specific project that has been approved by a recognised REC.

Example
A researcher requires whole blood for a research project. They are able to access blood samples from a diagnostic archive in a hospital biochemistry laboratory, which have been stored for the intended purpose of diagnosis and screening. Consent for the use of the samples for research was not obtained. The researcher can use these

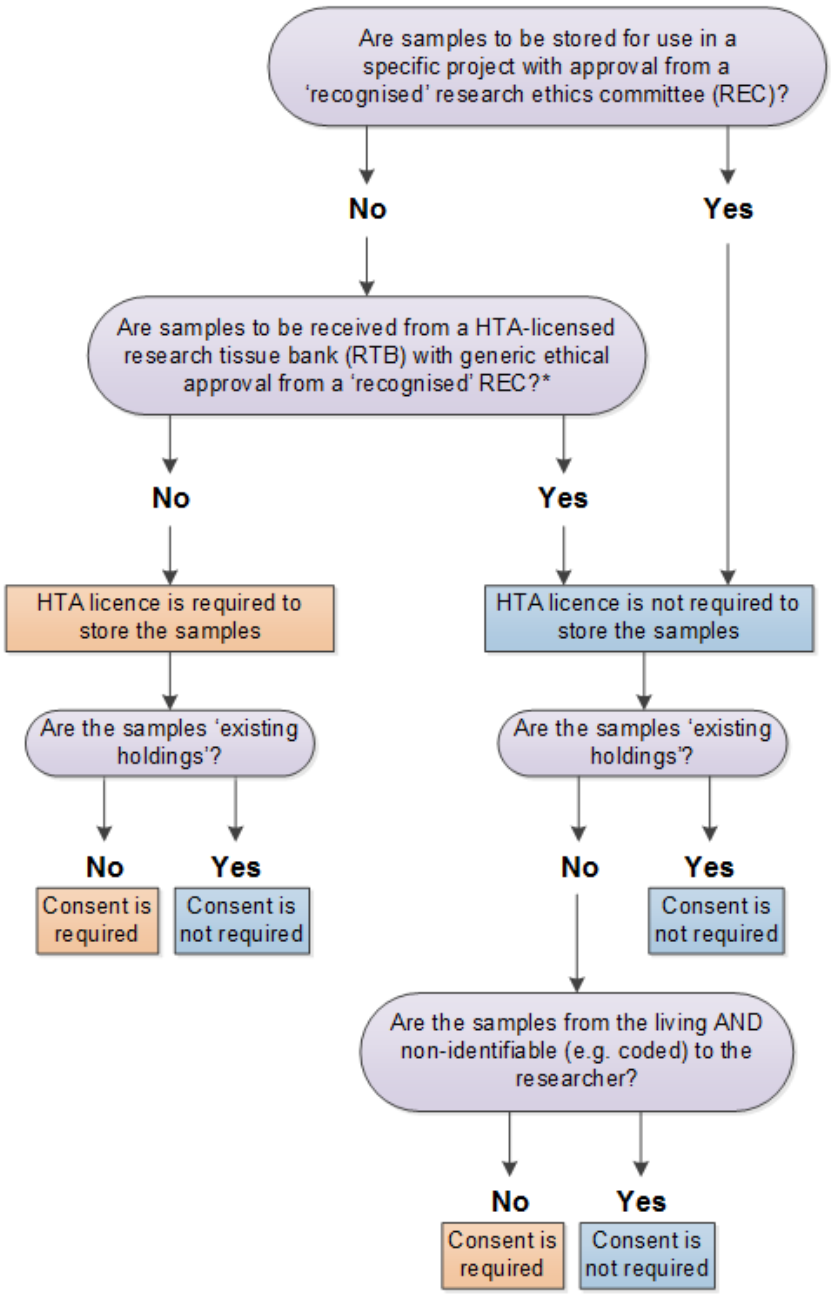
samples without the patients' consent, provided the samples are not identifiable to them and the specific project has been approved by a recognised REC.

Therefore, to facilitate the use of valuable human tissue in research, the HTA advises, in line with the MRC and HRA, that consent should be **generic** because this avoids the need to obtain further consents. It is still important however that consent is valid. If the intention is to store the tissue for an as yet unknown research purpose or as part of a tissue bank for research then this should be explained, setting out the types of research that may be involved, any wider implications and the arrangements for disposal of the tissue. If a donor objects to specific types of research, this must be respected, and it is important to inform donors how future research will meet the scope of the consent that they have given.

Note: samples obtained for an as yet unknown research purpose would not be able to be stored at UWE as we do not have a licence. If UWE researchers proposed to collect samples on this open ended basis, perhaps as part of a collaborative project, it would be necessary for the tissue to be stored off site (at a licensed premises), and only stored at UWE once covered by a favourable NHS REC opinion for a specific project.

Source: www.hta.gov.uk

The link between ethical approval and the licensing and consent exceptions for human tissue in research



*Please note the following:

- Some RTBs require external researchers to obtain project-specific approval from a recognised research ethics committee.
- RTBs need to be covered by a HTA licence because at least some of the tissue being stored is not for specific projects holding approvals from recognised research ethics committees.

8.2 Consent for received samples

Researchers receiving samples from collaborators or other institutions must never assume that generic consent (i.e. not limited to the scope of the

original project) **is in place**, and in all cases must obtain documented evidence that consent has been given for the transfer and proposed use of the relevant material in question.

In order to maintain good practice as defined by the HTA, it is important that where collaborating researchers wish to share or transfer any relevant material, they must ensure that the following is in place **before** the transfer of any material takes place:

- Check the terms of the consent given by the research participants, to confirm consent has been given for their donated sample to be sent to collaborators or other institutions in the UK and/or abroad; and if appropriate, if they consented for use in future ethically approved projects. If samples are being transferred to UWE from an external collaborator, it is the responsibility of the recipient UWE Project Manager to obtain the relevant documentation confirming the terms of consent.

- Where the recipient is to use the samples in a different project (i.e. not the one that they were collected for) and generic consent has not been given, the recipient must seek NHS REC approval for the use of the samples for their project. The recipient must give written assurance to the sender that ethical approval is in place for the recipient's project.

- If the appropriate consent for transfer is in place, the recipient should be informed in writing, including the terms of that consent. The sender should also agree, in writing, the terms of what the recipient is permitted to do with the samples and stipulate in the agreement that only the agreed analyses should be performed on the samples. These provisions would normally be laid out in a Material Transfer Agreement. You must contact the Contracts and Legal Team to arrange this (via the Head of Contracts: larry.rawlinson@uwe.ac.uk) and further details are given in Section 13 below.

- Samples must in all cases be sent in a coded form, so that no identifiable information is sent with them, unless there is explicit consent for transferring identifiable information from the research participant and this has been approved by an NHS REC. If identifiable information is sent subject to these requirements, the recipient must confirm that these data will be treated confidentially. The relevant material storage ledger must be updated to show when, where and to whom the samples are being transferred.

- The sender should inform the recipient of what should happen to the samples following recipient use (i.e. disposal or return). If disposal, the agreement should stipulate how they should be disposed of. Arrangements for disposal must also be outlined in the participant information sheet.

- In all cases, the sender must stipulate that the recipient is not at liberty to use the samples for their own commercial gain, or to send the samples to any other third party. This would normally be included in the Material Transfer Agreement.

- In all cases, the sender must inform the recipient how the sample is preserved and of any biological hazards associated with the sample, and the recipient takes responsibility for the appropriate management, appropriate preservation and handling of the sample. The MRC will not be liable for any harm caused to the recipient.

- In all cases, the sender should agree with the recipient how the donation of samples will be acknowledged in future publications – authorship if relevant, or acknowledgement. This would normally be included in the Material Transfer Agreement.

- Further guidance on the transport of human tissue samples is given in Section 16 below.

See also:

- HRA Consent and Participant Information Sheet Preparation Guidance: www.hra.nhs.uk/resources/before-you-apply/consent-and-participation/consent-and-participant-information/

- MRC's guidance including 'Personal information in Medical Research': www.mrc.ac.uk/documents/pdf/personal-information-in-medical-research/

- MRC 'Good research practice: Principles and guidelines': www.mrc.ac.uk/news-events/publications/good-research-practice-principles-and-guidelines/

8.3 Consent and Samples Sourced from Outside of the UK

The consent provisions of the Human Tissue Act do not apply to relevant material which has been imported into England, Wales or Northern Ireland. Nonetheless, the HTA considers it good practice to ensure mechanisms are in place in the source country for obtaining consent as part of the process by which the material is obtained. The requirements are set out in the HTA Code E: Research. **UWE researchers must comply with the guidance set out in this Code of Practice**.

Any researchers intending to import human tissue should be able to satisfy themselves and document the need for importing in terms of accessibility, quality, timeliness of supply, risk of infection, quality of service, cost effectiveness, or scientific or research need. Such documentation should be available for inspection by the HTA. For example, it may not possible to obtain sufficient numbers of high quality tissue samples from England, Wales or Northern Ireland for some diseases or genetic conditions. The importer should be able to provide policies and/or standard operating procedures demonstrating how informed consent was obtained. The register maintained by the person undertaking the import must retained for at least five years after disposal of the last sample recorded in it. Unless specified otherwise, disposal should meet the requirements of the HT Act as if it had been sourced from England, Wales or Northern Ireland.

UWE regards high standards in ethical consenting to be paramount in all research. The University will therefore only accept for storage human tissue (whether cellular or acellular) that has been ethically sourced. Ethical consenting must take place within the context of the particular country concerned, and the procedures will therefore vary. Whilst cultural sensitivities must be respected, this should not lead to anything less than excellent ethical standards being in place. This is particularly the case in relation to vulnerable groups, which in different contexts may include women, children, older or poor people, people from certain ethnicities or other social categories or those who are in a negative power relationship with researchers or gatekeepers. It is the UWE Project Manager's responsibility to ensure that samples are ethically sourced and consented and if there is any doubt, those samples should not be collected or imported as part of the project. Such ethical judgements can be complex, and guidance is available from the HTSC via the Officer.

Researchers should note that whilst the Human Tissue Act does not cover the import of tissue, it does cover the storage of such tissue once it is in the UK. Imported relevant material cannot therefore be held at UWE without approval from an NHS REC.

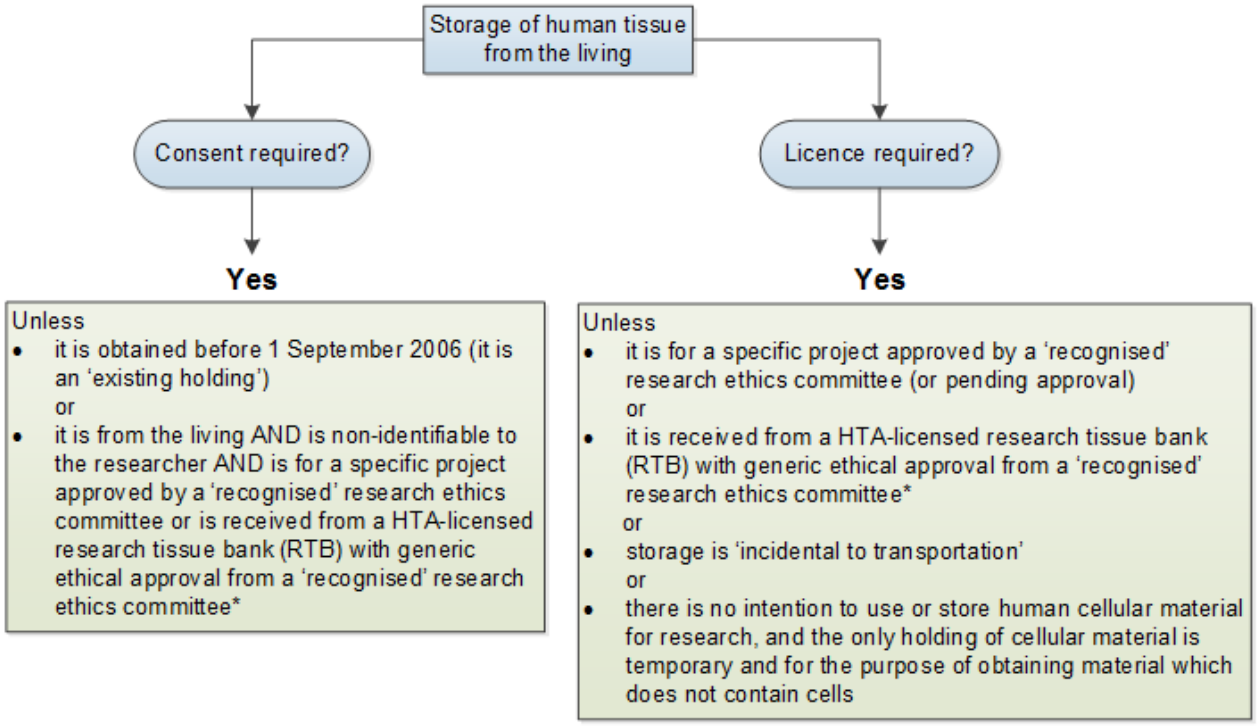
9. Storage of Human Tissue at UWE for research purposes: Legal Compliance and Exemptions.

UWE does not currently hold an HTA licence for storage of human tissue for research purposes (as defined by the Human Tissue Act). This means the licensable storage of relevant material for research at UWE must be covered by a valid, in date, NHS REC favourable opinion for a specific research project, or covered by the NHS REC approval of a Research Tissue Bank, prior to human tissue being brought on to UWE premises.

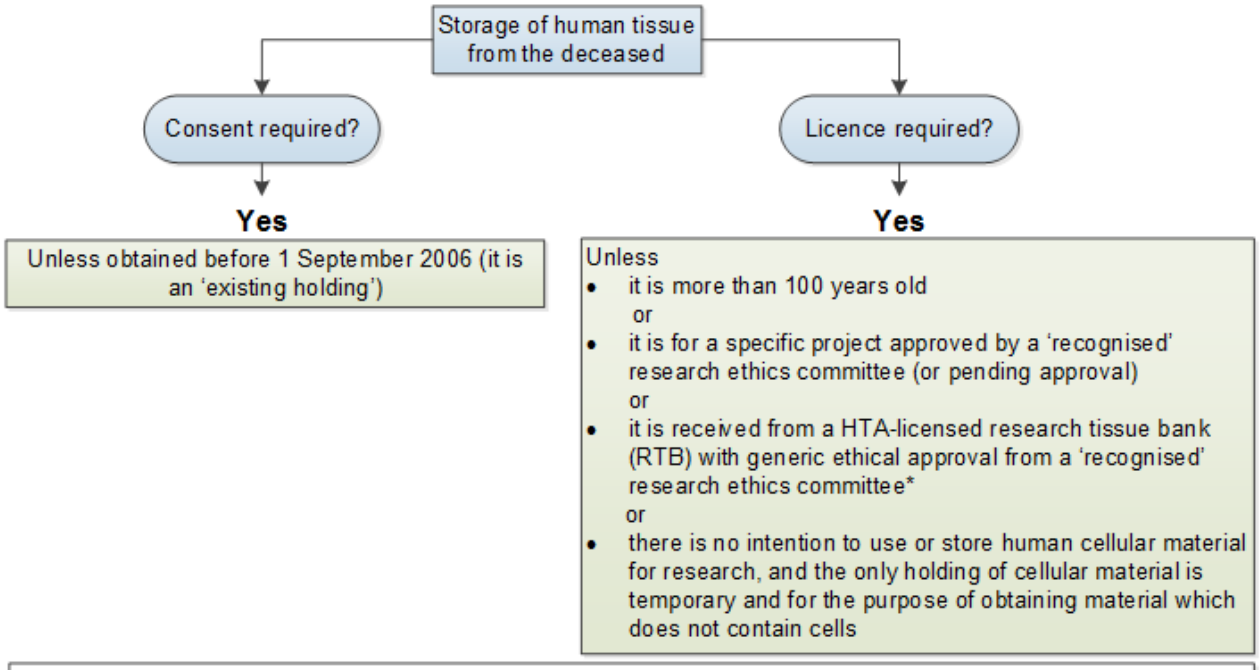
There are exemptions to the licensing requirements of the Human Tissue Act. In practice, it can often be complex to interpret whether a specific exemption applies, and UWE requires any UWE Project Manager proposing to bring human tissue on to UWE premises under an exemption to first seek guidance from the HTSC.
Existing holdings of relevant material (those held prior to September 1st 2006) may continue to be stored without seeking retrospective consent. However, continued storage will require a HTA licence unless the samples are being stored for use in a specific project which has been approved by a NHS REC **or** the samples are being stored for less than 7 days, after which they will be transported to another site **or** rendered acellular.

Different exemptions apply depending on whether the tissue is from the living or the deceased (i.e. whether the donor was living or deceased at the point that the tissue was removed).

Licensing and consent requirements for human tissue for research from the living



Licensing and consent requirements for human tissue for research from the deceased



*Please note the following for both flowcharts:

- Some RTBs require external researchers to obtain project-specific approval from a recognised research ethics committee.
- RTBs need to be covered by a HTA licence because at least some of the tissue being stored is not for specific projects holding approvals from recognised research ethics committees.

9.1 Licensing exemptions – living or deceased persons

i) **Storage incidental to transportation**

The licensing requirements for storage do not include storage which is incidental to transportation. This means that the storage of material while it is being conveyed from one place to another does not need to be licensed. This would normally be a matter of hours or days and no longer than a week.

Example
Skin biopsies for use in research are collected across a number of sites and batched before being sent to an establishment licensed by HTA for storage for research. The multiple sites collecting the biopsies do not need to be licensed as the storage is pending transportation to a licensed establishment.

If human tissue is being held while it is processed with the intention to extract DNA or RNA, or other subcellular components that are not relevant material (i.e. rendering the tissue acellular), it is viewed as analogous to the incidental to transportation exception. A licence is not required, providing the processing takes a matter of hours or days and no longer than a week.

Example
A researcher wants to undertake a study looking into immunological responses to breast cancer. To do this clotted blood samples will be spun down to collect the serum. As the blood will be spun down within a matter of days and any residual cells disposed of to leave serum that is not relevant material, the blood does not need to be stored under a HTA licence. Researchers must ensure that all red blood cells, white blood cells, and platelets are removed.

It is important to note that with the above exemption, you cannot commence your research during this period of time, even if the tissue would be rendered acellular by the first step of the research process. This exception under the Act is solely for specifically lysing cells, which must take place by a recognized means for so doing prior to the first step of your research.

If you wish to utilise this exception, you must seek guidance from the HTSC in advance. If considered appropriate, the HTSC may need to seek advice from the HTA, and will then advise you if you can proceed without NHS REC approval. You will, however, in any case need ethical approval from the relevant UWE Faculty Research Ethics Committee (FREC) or the University Research Ethics Committee (UREC), or NHS or Social Care Research Ethics Committee approval if involving NHS or Social Care patients.

Other examples where a HTA storage licence would **not** be required (but would need approval from a recognised REC):

Example 1
A whole blood sample is taken and this is then immediately sampled for blood lactate levels in the plasma, then the sample is disposed of about five minutes following the sample being taken.
Conclusion: No storage of relevant material for research would be taking place.

Example 2
A whole blood sample is taken and this is then immediately processed for various tests that day, some of which includes testing directly on the cells themselves. All samples are disposed of when the tests are complete, later that day.
Conclusion: No storage of relevant material for research would be taking place

Example 3
A whole blood sample is taken and made acellular immediately, and only serum is retained for research.
Conclusion: No storage of relevant material for research would be taking place.

Example 4
An experiment is conducted over a 6 day period. Whole blood samples are provided by volunteers throughout the sample collection period. All the samples are made acellular by day 7, with only serum being stored for research.
Conclusion: There is no intention to use or store human cellular material for research, and the only holding of cellular material is temporary (a few days) and for the purpose of obtaining research material which does not contain cells. The serum is the material which will be stored for research, and this does not require a HTA licence.

Example 5
A study has received approval from a recognised REC where blood samples are taken during a clinical trial.
Conclusion: No HTA licence is required to store samples for which REC approval has been obtained (see section ii below).

e) Example where a HTA storage licence would be required:
Blood samples (e.g. relevant material) from healthy volunteers are collected from two groups of participants as part of a research study over a two-day period. After each collection, the samples are stored in a refrigerator and then analysed for research, as a batch, once all have been collected. All samples are used and disposed of within seven days of the first collection. The project involves healthy volunteers and has **not** been approved by a recognised REC.

Conclusion: Although the storage period is for only 2-3 days, relevant material samples (whole blood) are being stored solely for the purpose of research within the scope of the Act; a HTA storage licence is therefore required. Please note that even if the research destroys the cells, this does not alter the point that prior licensable storage of relevant material for research would have taken place.

ii) **Project level approval via an NHS REC**

An exemption in the Act allows tissue and cells to be stored without a licence for a research project that has appropriate ethics approval (Section 1 (9) of the Human Tissue Act 2004)[1]. In addition, consent is not required to store and use tissue from the living for an ethically approved research project if it has been anonymised. Further details are given in the HTA Code E: Research:
The Regulations allow human tissue held for a specific research project approved by a recognised research ethics committee (or where approval is pending) to be stored on premises without an HTA licence. An application for ethical approval is pending from the point it has been submitted until the decision of the committee has been communicated to the applicant.

The HTA advises researchers to gain ethical approval before embarking on any research. An HTA licence should not be viewed as an alternative to ethical approval by a recognised research ethics committee.

In practice, this is the route by which most research using human tissue in UWE premises will be authorised under the Human Tissue Act. The UWE Project Manager must submit an application to a NHS REC via the National Research Ethics Service for each research project, and human tissue should only be brought onto UWE premises once a favourable opinion has been received.

Example
A dental teaching hospital establishes a bank of human teeth to carry out research into tooth erosion, wear and hypersensitivity and control of dental plaque and staining. The teeth will be donated with consent from the donor after routine dental extraction. The hospital obtains a storage licence from the HTA as well as generic ethical approval to operate as a research tissue bank. An individual researcher receiving teeth from the bank does not need to make further applications for project specific ethical approval or for a HTA licence, provided the research project falls within the research aims, material disposal terms, and terms of donor consent specified in the hospital's research tissue bank ethics approval. In this way, valuable human tissue for research is controlled and made more accessible to a number of research projects.

[1] https://www.hta.gov.uk/policies/licensing-exemptions

Even though the regulations permit human tissue being stored at UWE whilst an NHS REC research project application is pending, normally UWE requires a favourable opinion to be in place before tissue (either from the living or from the deceased) is brought onto site. This is because UWE does not have a licence, so if an NHS REC application was unsuccessful, this would place UWE immediately in breach of the legislation.

iii) **Research utilising human tissue supplied by a tissue bank**

Some specific research ethics committees (RECs) have been authorised to give broad ethics approval for research tissue banks which will then be required to work under HRA standard operating procedures (SOPs). This means that a specified remit of work is permitted without the need for further individual project specific approvals. The tissue in these research tissue banks must be stored on HTA-licensed premises.

This means that, subject to certain requirements, researchers may be able to access human tissue from a tissue bank and store it on UWE premises without obtaining an individual project approval from an NHS REC. However, a copy of the Tissue Bank's NHS REC approval should always be obtained by the UWE Project Manager, and submitted when the project ethics application and approval (usually ethical review of the Project is undertaken by the tissue bank prior to them agreeing to provide tissue) is presented to UWE UREC / FREC for ratification (UREC or FREC ratification will always be needed). Evidence of the specific permission that has been granted by the tissue bank for the research must be included. The UREC/FREC number will be needed for registration on the *UWE Human Tissue Research Register*. All of the above information should be retained on the Project file.

All tissue obtained from a tissue bank must have a Material Transfer Agreement with a start and end date, and arrangements in relation to any tissue left at the end of the projects must be specified.

iv) **Research utilising human tissue supplied by a diagnostic archive**

Diagnostic archives involve tissue taken from the living for diagnosis **only** and may be subsequently stored without the need for a HTA licence provided that no licensable activity is taking place. However the storage of tissue for a 'scheduled purpose' must be on licensed premises. If a diagnostic archive releases tissue for research occasionally upon request, its status as a diagnostic archive is clear. However, if tissue is expected to be released on a regular basis then the diagnostic archive status may no longer apply. If a diagnostic archive invites applications for the release of samples and/or advertises the archive as a resource for researchers, then the HTA will consider it a tissue bank and requirements in the above section will apply.

v) **Research using 'finger prick' blood tests**

Where a 'finger prick' test is taken, and used immediately and then immediately disposed of (autoclaved within five days at the absolute maximum), this does not fall within the Human Tissue Act as the tissue (in this case blood) is not considered by the HTA to be stored. However, such research will need ethical approval from UREC/FREC, and issues such as consent and participant information will need to be considered as for any study involving human participants. In addition, a sample ledger must be maintained by the researcher which details each sample taken and the date it was autoclaved.

Because the University does not have a Human Tissue Authority (HTA) licence, it is not permitted to host a tissue bank. UWE researchers should never apply for funding to do this on UWE premises, nor attempt to establish a tissue bank.

9.2 Licensing exemptions – deceased persons

Storage of material which has come from the body of a deceased person is exempt if the licensed activity relates to the body of a person who died before 1st September 2006and at least 100 years have elapsed since the date of the person's death. **However, UWE Research Ethics Committee approval will always be necessary**.

Storage of relevant material which has come from the body of a deceased person (irrespective of the date on which that person died), is exempt from licensing if the person storing it is intending to use it for the purpose of 'qualifying research' or for a specific research project for which such ethical approval is pending. Qualifying research means research which has been ethically approved by a recognised REC. This can either be a REC established under and operating to the standards set out in the governance arrangements issued by the UK Health Departments or an ethics committee recognised by the United Kingdom Ethics Committee Authority (UKECA), to review clinical trials of investigational medicinal products under the Medicines for Human Use (Clinical Trials) Regulations 2004. This means that use of material from the deceased for research will usually require approval by an NHS REC.

9.3 Licensing exemptions – living persons

There are a number of licensing exemptions which relate to living persons, but the most relevant for research is **'qualifying research'** (see definition above i.e. you don't need a storage licence if the project has been approved by an NHS REC).

9.3 Acellular Material

There are several possible permutations here:

- Tissue may already have been rendered acellular before being brought on to UWE premises for storage, in which case it is not covered by the Human Tissue Act.
- Tissue may be cellular when brought on to site and may then be lysed whilst at UWE, by recognised means, within a maximum of a week, and before the research commences. The storage of this material would therefore be considered 'incidental to transport' and a favourable NHS REC opinion would not be needed (see 9.1 above).
- If tissue is cellular when brought on to site and the research commences before the cells are rendered acellular (even if the course of the research would cause the cells to be rendered acellular within a week of arrival), then an NHS REC (REC) favourable opinion will be needed at the time the tissue is brought to UWE to enable UWE to comply with the Human Tissue Act, as at the point that research commences, the tissue is considered relevant material and a favourable NHS REC opinion will be necessary to permit storage for any period at UWE.
- Once cellular tissue stored at the University has been lysed, it is no longer considered relevant material. However, if a favourable opinion from an NHS REC was obtained in order to enable initial storage of the cellular material at UWE, then the provisions of that favourable opinion continue to be in force.

Human tissue, whether cellular or not, is a precious resource which must always be treated with respect. **UWE therefore requires the use of acellular material to be registered on the *UWE Human Tissue Research Register*, and its use always to undergo ethical review.** Further detail is provided below at Section 11.

9.4 Xenotransplantation

Xenografts are cells, tissues or organs that are transplanted from one species to another. The use of human tissues and cells in animals is not considered a method of storing human tissue or cells and therefore does not require a storage licence. However, where human tissues and cells are being stored for a scheduled purpose **before** they are transplanted into a recipient species, a storage licence may be required. When consent is obtained for tissue and/or cells to be used in research and it is known at the time of obtaining consent that this would involve the transfer of material to animal models, this should be explained to the individual and consent should be obtained for this.

10. Requirements for UWE Researchers working with HTA relevant materials not on UWE premises

10.1 A Favourable Ethical Opinion (including consent) must always be in place to cover the specific use by a UWE researcher acting in their capacity as a UWE Researcher.

- Where staff or students hold another role outside of their UWE researcher role which would enable them to access and use human tissue in ways that any other UWE researcher would not normally have access to or be permitted to use, their external role is of no relevance as they are acting under the auspices of UWE at the time of the research activity/access to HTA Relevant Materials, and they must only do what is permitted as a UWE researcher[2]. Therefore, where human tissue is being used offsite for research purposes (not on UWE premises) but by a UWE researcher or student, there must always be in place a formal agreement between UWE and the site where tissue is being accessed where the tissue holder makes clear that the UWE staff member or student can legitimately access the tissue concerned for the purposes of research under the auspices of UWE.

- UWE FREC must always ratify a favourable opinion from an external REC, even if the research is taking place offsite, and that favourable opinion must adequately cover for the research being conducted by the UWE researcher (and normally FREC will wish to see that the researcher, and UWE, were named in the ethics application).

10.2 A Collaboration agreement of a type appropriate to the circumstances must be in place between the institutions prior to any HT being accessed not on UWE premises by UWE researchers (including students) in their capacity as UWE researcher for research.

- The collaboration agreement should specify the responsibilities of UWE and the host organisation in relation to the research

[2] For example, a student based within the NHS, who has permitted access to blood test samples in their normal job role for diagnostics or quality assurance, can only use this tissue for their UWE research (when they are wearing their 'UWE researcher hat') if there is consent in place for this new use (i.e. use by someone outside the NHS i.e. a UWE researcher) and ethical approval for the research. The Human Tissue Authority specifies that residual blood or tissue from the living can be used without consent only if the research is ethically approved by a recognised Research Ethics Committee and the researcher cannot link the blood or tissue to the patient. Consent is needed for research where the tissue is from a deceased person. NB also FREC approval is needed for evaluation research even where NHS REC approval is not, as UWE considers evaluation research should comply with the same ethical standards as other kinds of research, and approval will not be granted unless the samples are anonymised (by someone else) before the UWE researcher receives them (thus complying with the same principles of anonymity and ethical approval that are set out by the HTA). If you are uncertain, please consult with your FREC.

- If a researcher is removing samples from UWE to work on them elsewhere (where participant consent permits this) an MTA will always be needed between UWE and the entity the samples are transferred to and must cover issues such as any instructions for storage and disposal/return as appropriate.
- If relevant material is to be brought on to UWE premises then this must also be covered by an MTA and by an appropriate NHS REC favourable opinion.
- Where a student is conducting research on human tissue away from UWE premises, the collaboration agreement (which may be a Placement agreement) must cover the responsibilities of UWE and the other organisation in relation to the Student using human tissue, including the responsibility for obtaining all appropriate ethical approvals, and supervision of the Student.
- Collaboration agreements should, where appropriate, cover Sponsorship arrangements, and must cover issues such as insurance and Health and Safety.
- Collaboration agreements should include assurances that human tissue has been ethically sourced.

10.3 Where a UWE researcher is working overseas, evidence will be needed that adequate ethical procedures were followed in collecting the samples being used.

- A favourable ethical opinion must be in place to cover the specific use by the UWE researcher, and UREC/FREC must see adequate evidence of this.
- Whilst good ethical practice must take into account cultural norms and practices in the country concerned, and there may be differences in how ethical practice is expressed, there must also be a minimum ethical expectation in line with what UWE would expect to see in the UK. UWE researchers should be able to be assured that samples have been collected ethically and appropriate local permissions for their use by third parties are in place. UWE researchers may not participate in collecting samples, or use samples collected by others, otherwise. Due diligence would suggest that UWE should make the same considerations as it would if we were importing the samples for use in the UK.

10.4 Where UWE leads a project, but the human tissue element is conducted elsewhere by researchers within a partner organisation, the project must be on the UWE Human Tissue Register. The principle here is that UWE thereby has oversight of all research projects for which UWE has overall responsibility.

11. Ethical Approval for research

All Research by UWE researchers using Human Tissue (as defined by the HTA) at any location and/or storing human tissue on UWE premises requires ethical approval.

Researchers are expected to familiarise themselves with the current guidance provided by the Health Research Authority (HRA) on Human Tissue Research, to be found at:
www.hra.nhs.uk/resources/before-you-apply/types-of-ethical-review/ethical-review-of-research-involving-human-tissue/

A summary table of ethical approvals required for different types of human tissue research within UWE is provided in Annex 7.

It is the responsibility of the UWE Project Manager to ensure appropriate ethical approval for the research is in place. Supervisors of PhD students are responsible for checking and approving a student ethics application before submission. Masters and undergraduate students are not permitted to submit applications for NHS REC approval. This should be done by their supervisor. Research can only commence once an appropriate favourable ethical opinion has been received from, or in the case of NHS REC or other external ethics committee ratified by, FREC/UREC.

If a Masters or undergraduate student wishes to conduct research using human tissue, this would normally have to be covered by an existing NHS REC approval, or depending on the nature of the project, an application would need to be made to FREC / UREC.

Additionally, all students conducting research with human tissue must be registered on the UWE *Human Tissue Research Register*. See Section 14 for further details.

The University's policy relating to ethical review aligns with Health Research Authority guidance. A core function of the HRA is to protect and promote the interests of patients and the public in health research and to streamline the regulation of research.

In relation to human tissue, an application to an NHS REC via performs three functions:

- Firstly it requests permission to conduct research with tissue obtained from NHS patients, (or those in Social Care).

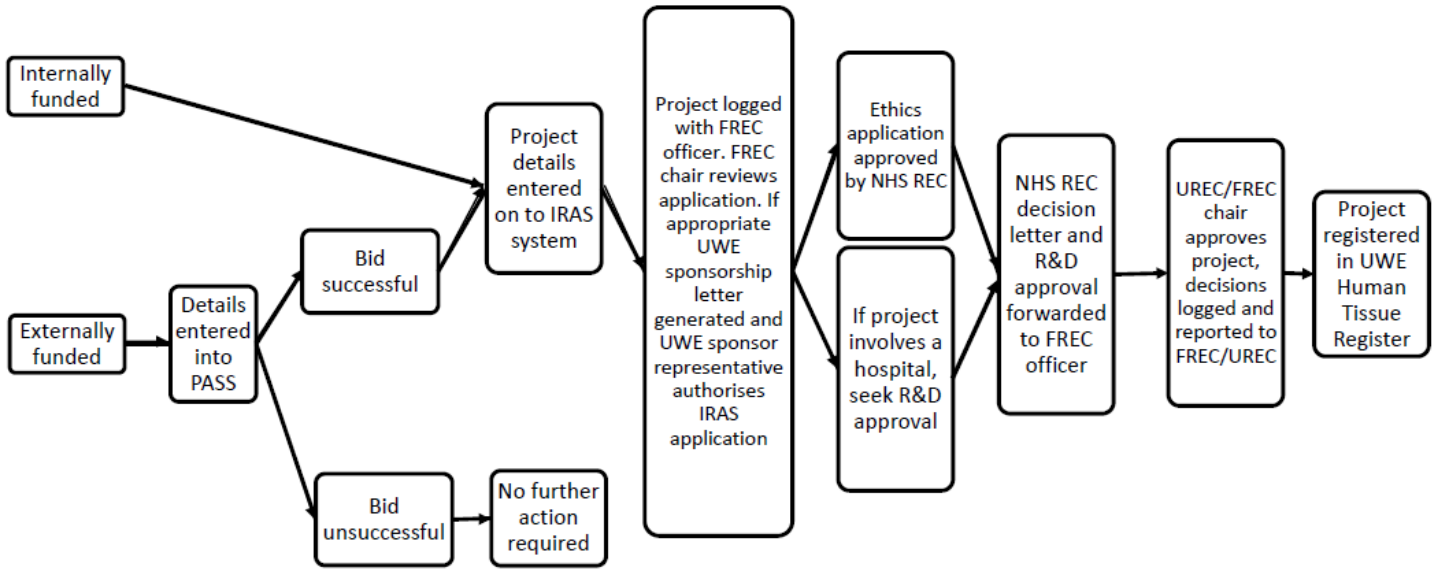
- Secondly, it requests ethical review of a specific project and permission to use human tissue or cells in that project.
- Thirdly it seeks approval for storage of the tissue or cells at UWE, as the only permissible alternative to UWE holding a licence for research.

The application should make clear that UWE is a site for storage and or use of the tissue or cells, even if the project is a collaboration with researchers based at other sites, whether or not UWE or a collaborating institution is taking the lead in submitting the application.

Guidance about ethical review is provided overleaf, and the UWE pathway to ethical approval is illustrated by the following flow chart:

Category C project

EXTERNALLY/INTERNALLY funded project using **HUMAN TISSUE** as defined by the Human Tissue Act



July 2015

Pathway to ethical approval for externally/internally funded project using Human Tissue as defined by the Human Tissue Act 2004

Taken from the UWE Research Ethics webpages:
www1.uwe.ac.uk/research/researchethics/applyingforapproval.aspx

i. If research involves NHS patients (including tissue or organs obtained from them), researchers will need to obtain NHS REC approval. This is a DH requirement for all research involving NHS patients, whether or not human tissue is involved. **Researchers will also always need Research and Development Management approval**. Once researchers receive their REC (and HRA if applicable) approval letters they should forward these, along with supporting documentation, to each NHS trust involved in the research. The HRA website provides guidance on applying for REC/HRA approval.

ii. An NHS REC is a 'recognised REC' under the terms of the Human Tissue Act and therefore will also consider proposals using human tissue not involving NHS patients. If researchers intend to collect any relevant material and store it on UWE premises, involving NHS patients or not, then NHS REC approval will be needed. **This is essential as UWE does not have a human tissue licence**. NHS REC approval is the mechanism that is approved by the HTA to permit storage of human tissue for research on premises that do not hold a licence.

iii. All research at UWE using human tissue must undergo ethical review. In most cases, because of the need for a licence for storage (to which NHS REC approval is an alternative), or because NHS or social care participants are involved, this will mean that ethical review takes place via an NHS REC. In exceptional cases where NHS REC approval may not be necessary (for example a project does not involve NHS or Social Care patients and cellular material will not be stored at UWE for longer than a week) then **FREC/UREC approval** (or ratification of external ethics committee favourable opinion, such as that of a partner university, see below) **will always be necessary prior to the commencement of the research**.

iv. UWE operating procedures for ethical review permit review by a properly constituted external ethics committee. Where external review has taken place, via NHS REC, or, for example, via another University's ethical review processes, then **FREC/UREC ratification will always be necessary**. This ensures that any local issues are properly covered, and that the University has evidence that the research using human tissue on its premises, and/or research undertaken by its researchers, is appropriately covered by a favourable ethical opinion.

v. Good practice is always to have one ethical review for the whole project. Wherever possible, this must be followed.

- Where this is not possible (for example where tissue is being provided to UWE researchers as a result of tissue being collected for a large trial elsewhere), the UWE research (i.e. the UWE use of that tissue) must have ethical review.

- If the tissue is cellular when it is brought on to UWE premises, then ethical review must be through NHS REC and the NHS REC approval should specify UWE as a site for storage and use of the tissue.

- If a project:
  a. is using acellular material brought on to UWE premises, or
  b. is storing samples that will be transported on or rendered acellular within one week (prior to the commencement of the research), or
  c. is storing samples that do not fit the HTA definition of 'research'
  d. **and** there is no other reason that the research must be considered via an NHS REC or another external ethics committee then a FREC/UREC application will need to be made for ethical review of the specific project now being undertaken. The UWE Human Tissue Ethics Application Form in **Annex 4** must be used for this purpose and applications made using the standard UWE Ethics Application Form **will not be accepted**. In the case of collaborative research, it would also be allowable for review to have taken place via an external ethics committee and ratified by FREC/UREC, as discussed above.
- In cases where the project ethical review does not cover removal of samples (such as where samples were collected as part of another project), evidence will need to be provided prior to FREC/UREC ratification that there was appropriate ethical review covering the removal of the samples, and that consent was given which permits the proposed use for the project.

vi. Lead responsibility for ethical review should always be clearly established at the outset, including potentially sponsor responsibilities.
  - If you are a collaborator on a project using human tissue being led by another institution and for which UWE is not a sponsor, and is not leading the ethical review process, it is essential that UWE is aware of the content of any ethics application submitted to an external REC.
  - It is the responsibility of the UWE Project Manager to ensure that the research has appropriate ethical approval, and that a copy of the ethics application and favourable opinion (including **all** supporting documentation) are held on the project file and submitted as part of the information presented to FREC/UREC for ratification. Supporting documentation would usually include protocols, consent forms and participant information sheets, and copies of HRA/REC approvals and NHS Trust R&D Management approvals (if applicable).
  - This enables UWE to be certain, in the case of NHS REC approval, that the favourable opinion provides the necessary permissions for tissue to be stored at UWE, and in the case of any external ethical review, that the activities of UWE researchers are appropriately covered, and that the human tissue has been ethically sourced, and consenting permits the intended use by UWE researchers.
  - **UWE Researchers should not begin to conduct research on human tissue samples at any location until FREC/UREC ratification is received**.

vii. Where tissue is brought on to UWE premises in an already acellular state, there will always need to be evidence that the original cellular material was collected ethically, by means of NHS REC or other ethics committee approval.

- Prior to any use of acellular samples, a current favourable ethical opinion must be in force for the proposed project.
- If UWE researchers or their project collaborators, as part of the project, plan to render samples acellular off site at a licenced premises, a current favourable ethical opinion must be in force for the project for which this process is being undertaken i.e. cells should not be rendered acellular as part of a project without a favourable ethical opinion being in place.
- All acellular materials must be registered on the UWE *Human Tissue Research Register* and appropriate UWE ethical approval must be sought before they can be used.

viii) Applications to an NHS REC using the online national Integrated Research Application System (IRAS) system should always be sent to RBI Committee Services in UWE Research, Business and Innovation (RBI) **before** submission (researchethics@uwe.ac.uk).

- Where a sponsor letter is required, applications will be checked by the Chair of FREC/UREC before the sponsor letter is prepared and authorisation given for it to be submitted.
- The decision to act as Sponsor is an active decision, and you should not assume that permission will be granted. You are strongly advised to seek advice from the FREC/UREC Chair in advance of submitting your NHS REC application for approval. Please note that the changes to HRA processes in 2016 mean that you cannot submit your NHS REC application without Sponsor authorisation.
- Research can only proceed when an NHS REC favourable opinion has been received and ratified by FREC/UREC and the project, including this permission, has been **registered** on the UWE *Human Tissue Research Register* with the HTSC Officer in RBI (see Section 14 below).
- A copy of the application with all supporting documentation (including questionnaires, protocol, consent forms and patient information sheets), and favourable opinion must be provided to RBI Committee Services (researchethics@uwe.ac.uk) for FREC/UREC ratification prior to any use of the human tissue covered by that favourable opinion, or the tissue being brought on to UWE premises.
- Copies of the documentation, including the application and supporting documents, and the favourable opinion and any correspondence in relation to conditions, must always be held on the project file by the UWE Project Manager.

ix) Primary cells used for stem cell derivation (e.g. somatic cells, foetal cells, haemopoetic stem cells) fall within the Human Tissue Act while the cell lines

derived from them do not. Gametes and embryos used for stem cell derivation fall within the HFEA Act and cell lines derived from them must meet the requirements of the UK Stem Cell Bank and human embryonic cell lines must be approved for use by the UK Stem Cell Registry. Researchers are expected to follow the MRC Code of Practice for use of Human Stem Cell Lines at: www.mrc.ac.uk/documents/pdf/code-of-practice-for-the-use-of-human-stem-cell-lines/. For further guidance see: www.mrc.ac.uk/research/initiatives/regenerative-medicine-stem-cells/regulation-and-governance/

x) If you obtain human tissue samples from a licensed Research Tissue Bank which has generic ethical approval you will need to provide a copy of the Tissue Bank's NHS REC letter of favourable opinion, a copy of your application to the Tissue Bank, and evidence from the Tissue Bank that your project has passed through ethical review, and the conditions under which you have been granted permission to use the tissue (usually as part of an Material Transfer Agreement) to RBI Committee Services (researchethics@uwe.ac.uk) for FREC/UREC ratification prior to any use of the human tissue covered by that favourable opinion, or the tissue being brought on to UWE premises. Research can only proceed when the project, including this permission, has been registered with the HTSC Officer in RBI (see Section 14 below).

NHS REC approval must be current in order for human tissue (as defined by the HTA) to be legally held on UWE premises. It is the responsibility of the UWE Project Manager to ensure that cellular material is not held on UWE premises past the end date of the project

xi) Researchers conducting projects with primary cell lines do not need to seek ethical approval; however they **must** be able to demonstrate that valid NREC approval was in place to cover the initial removal of the cells, and this must be provided to FREC/UREC for ratification before any research commences. Research involving commercial cells lines does not require ethical approval (unless there are other ethical issues involved in the project) but must be registered on the UWE Human Tissue Register.

The use of stem cell lines (whether sourced commercially or from a bank) must comply with the MRC Code of Practice for use of Human Stem Cell Lines at: www.mrc.ac.uk/documents/pdf/code-of-practice-for-the-use-of-human-stem-cell-lines/, and would need FREC/UREC approval.

xii Once an NHS REC favourable opinion has been given, sponsors and investigators must follow the important guidance set out by the National Research Ethics Service.

Failure to follow the guidance could lead to the NHS REC reviewing its opinion on the research. The key points are given below:

- It is assumed that the research will commence within 12 months of the date of the favourable ethical opinion. If the research does not commence within 12 months then the Chief Investigator must write to the NHS REC that gave the original favourable ethical opinion to give an explanation for the delay.

- It is anticipated that the project will proceed on the basis outlined in the NHS REC application, especially the Protocol. Any divergence from this may need to be the subject of a major or minor amendment (www.hra.nhs.uk/research-community/during-your-research-project/amendments/), or be covered in the Project's annual report.

- The Chief Investigator should submit a progress report to the NHS REC 12 months after the date on which the favourable opinion was given, and these should be submitted annually thereafter. The format for progress reports is prescribed by NHS REC and published on the website: http://www.hra.nhs.uk/resources/during-and-after-your-study/nhs-rec-annual-progress-report-forms/. Copies of annual reports should be held on the project file by the UWE Project Manager and also sent to the UWE HTSC Officer.

- If a substantial amendment is to be made, then this should not be implemented until a favourable ethical opinion has been given by the NHS REC, unless the changes to the research are urgent safety measures. Copies of the correspondence with the NHS REC should be held on the project file by the UWE Project Manager and also sent to the UWE HTSC Officer. Amendments will be recorded on the UWE *Human Tissue Research Register* and recorded by FREC / UREC.

- At the end of the study, the Chief Investigator should notify the NHS REC in writing that the research has ended within 90 days of its conclusion and send a copy to the UWE HTSC Officer for recording on the UWE *Human Tissue Research Register*. The conclusion of the research is defined as the final date or event specified in the protocol, not the completion of data analysis or publication of the results.

- A summary of the final report on the research should be provided to the NHS REC within 12 months of the conclusion of the study. This should include information on whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research including any feedback to participants.

xiii) The end date of a project is usually defined in the Protocol. You are encouraged to give some thought to how you define the end date. If you give a precise date, then the favourable opinion will expire on that date. There are, however, other ways of

defining the end of your project, such as 'when 200 subjects are reached'. You should consider a definition which gives you sufficient flexibility (for example should your research take longer than anticipated, or start later than anticipated) but which is still clear enough that a project end can be determined. It is possible to extend the end date of a project if the work as defined in the protocol has not been completed. This can be done through the annual reporting process. You should, however, take care not to undertake new work that was not covered by the original NHS REC project application.

xiiv) The end date should not be so open ended that this effectively means you can 'bank' your tissue for future use, the NHS REC approval is only approval for a specific project.

xv) You are permitted to retain tissue for a period of one year after your project end date for analysis or verification of research data. You should ensure that the purposes for which you are retaining tissue clearly fall within this description. You must dispose of (destroy or move to a licensed facility, depending on consent and permissions) any tissue before the end of this one year period as to continue to hold it beyond this point, without a new project NHS REC, would be unlawful. You should notify the UWE HSTC Officer when the samples have been destroyed.

xvi) It is increasingly seen as unethical to destroy human tissue samples which have consent for further use. If you wish to make further use of your samples, and you have consent to do so, then you must submit a new NHS REC application **before the end date of the existing project**. You are encouraged to consider at the outset of your study if your samples can, and should, be moved to a licensed facility (outside UWE) for re-use by others at the end of your project.

12. Staff and student volunteers

Researchers intending to use samples from the university's staff or students must ensure that a number of regulatory standards are met to reduce the risk that people feel pressured or coerced to donate:

a) a confidential coding system, so that donors cannot readily be identified by their colleagues;
b) donors should be able to withdraw their consent at any time, without any reason, without their decision having any negative effect on their relationship with colleagues or their conditions of employment or enrolment;
c) donors of samples with desirable biological characteristics should not be unfairly targeted;

d) donation thresholds should be established, and donation quantities monitored, such that donors do not donate excessively;
e) where donations are likely to be repeated, appropriate consent should either be sought afresh or reconfirmed, depending on whether the information needed to support the consent process has changed. In addition, establishments need to consider other risks, such as whether the lifestyle or medical history of the donor has changed since their previous donation. This may be important to protect both research staff (for example with regard to exposure to potential infectious risks) and donors (such as where their health status precludes donations).
f) any requests for external companies to access our students must come through the research governance office.

Example Students on a sports science course are being asked to give a blood sample in order to take part in research into the link between stress and exercise. For the consent to be valid, the students must be given sufficient information so they can give their consent voluntarily, having made an informed choice about whether they want to participate in the research or not.

It is particularly important to note that any such requests MUST be covered by a current favourable ethical opinion, and volunteers should never be approached directly by their supervisor or line manager. Volunteers must feel able to say no, and researchers must ensure that the arrangements set in place for seeking volunteers facilitate this, and in no way pressure volunteers to participate. It is also important that there is management approval for this activity, and in UWE's case, this means approval of the Executive Dean for your faculty, which should only be granted when evidence of a current favourable ethical opinion is provided. Where it is planned to use healthy volunteers as a control group, this should be included in the ethics application for the main study.

There are specific requirements which must be complied with in relation to asking staff to volunteer human tissue. The University endorses the arrangements set out in the MRC Guidance note 'Guidance for staff asked to volunteer blood and/or other samples for research'. Any researcher wishing to utilise staff volunteers must follow the provisions of this guidance note: https://www.mrc.ac.uk/documents/pdf/guidance-for-staff-asked-to-volunteer-samples/ . In line with the MRC guidance, we strongly advise against the use of one's own tissue or cells for research purposes, and you will need the approval of the Executive Dean for your faculty should you wish to do so.

If a researcher plans to use their own tissue or cells for research, then this must be covered by an appropriate NHS REC approval, to enable the tissue or cells (e.g. blood) to be held on UWE premises (once outside the body). In any case, UWE will always require ethical review of such situations, and will wish to consider issues

including whether appropriate arrangements are in place for removal of the tissue (such as blood), whether the researcher planning to use the tissue has been placed under any pressure to do so.

13. Contractual arrangements with funders and collaborators

In human tissue research, as for all research, appropriate contractual arrangements must be in place with funders and collaborators. The Contracts and Legal Team lead on agreeing these, and will work with you in relation to the contract terms which need to be included. You should avoid agreeing issues which will form part of the contract until you have received guidance from the Contracts and Legal Team.

If human tissue is to be transferred between UWE and a third party organisation, there will need to be a Material Transfer Agreement in place. You must contact the Contracts and Legal Team to arrange this (via the Head of Contracts: larry.rawlinson@uwe.ac.uk).

14. UWE Human Tissue Research Register

All research using human tissue must be registered on the UWE *Human Tissue Research Register*, whether within the scope of the Human Tissue Act or not. This includes all types of research, using relevant and non-relevant material.

The UWE *Human Tissue Research Register* is maintained by the Human Tissue Sub-Committee Officer. The format of the Register and procedures for updating the Register are given in the UWE *Human Tissue Records Management Manual*, which can be found at:
http://www1.uwe.ac.uk/research/researchgovernance/resourcesforresearchers/humantissueresearch.aspx

i) 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.
ii) All UWE Project Managers must register their project on the UWE *Human Tissue Research Register* before they bring samples onto UWE premises. This will ensure that required ethical approvals are already in place.
iii) The Register of projects that fall within the scope of the HT Act is presented to the Human Tissue Sub-Committee at every meeting and committee members can raise issues or concerns that they have with any project on the register.

15. Documentation and record keeping

The UWE *Human Tissue Research Records Management Manual* (found at: http://www1.uwe.ac.uk/research/researchgovernance/resourcesforresearchers/humantissueresearch.aspx) 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 at UWE.

The Manual includes details of project information and personnel records that the UWE Project Manager must maintain on the Project File for all human tissue research projects.

The Manual also includes procedures for managing and recording the locations where human tissue samples are stored at UWE.

16. Transport of Relevant Materials

Human tissue **must not be transported onto UWE premises** until all appropriate ethical approvals are in place (including UWE REC ratification of any external REC favourable opinion); NHS R&D approvals are in place (where required), and the project is registered on the UWE *Human Tissue Research Register*.

Once all appropriate approvals are in place, human tissue samples may be transported onto UWE premises in accordance with the detailed *Standard Operating Procedure: Transport of Human Tissue (Relevant Material)*, which can be found at: http://www1.uwe.ac.uk/research/researchgovernance/resourcesforresearchers/humantissueresearch.aspx

These procedures also apply to any onward transport of the tissue during the course of the project, and to the onward transport or return of tissue at the end of the project. The UWE Human Tissue cover letter in Annex 6 **must** be used for the onward transport/return of any samples. Documented evidence of what was sent and received by all parties must be retained, and this should be clearly recorded in the Sample Ledger for each project (see UWE Human Tissue Records Management Manual at: http://www1.uwe.ac.uk/research/researchgovernance/resourcesforresearchers/humantissueresearch.aspx)

When transporting relevant material, researchers must always be mindful of the Human Tissue Act and the Human Tissue Authority (HTA) *Codes of Practice* to ensure that donated human tissue is treated with respect in accordance with the wishes of donors or their relatives.

Note: All relevant material (human tissue), even that from healthy donors, is potentially infectious material. The HSE recommendations are that all human tissue should be treated as a minimum as a hazard group 2 (HG2) infectious agent and should therefore be transported with sufficient security to contain a group 2 bio-hazard spill. Further details are given in UWE *Standard Operating Procedure: Transport of Human Tissue (Relevant Material).*

17. Disposal of Relevant Material

All research at UWE using relevant material will be carried out under the terms of a NHS REC ethical approval, where the disposal methods will be clearly defined in the terms of the ethical approval. Processes should be in place to inform donors how their tissue will be disposed of after use. The HT Act permits disposal of surplus tissue as waste. The HTA recommends that human tissue is bagged separately to clinical waste; however it is not necessary for individual tissue samples to be bagged

and disposed of separately. While is it the usual practice for relevant material to be disposed of at the end of a study, bear in mind that you may be required to return all surplus material to the hospital where it was collected, or to the tissue bank that supplied the relevant material for your study.

Please be aware that it is increasingly considered to be unethical to dispose of donated human tissue which may be still be of use in a further study. Existing donated relevant material should be considered for use in a new project, providing it is feasible and appropriate to do so and only where the participant consent and conditions of use permit the use of the donated tissue for the new proposed research purpose. If you wish to retain surplus human tissue at UWE beyond the expiry of your current ethical approval (providing the consent and permissions relating to the relevant material permit retention) you **must** apply for ethical approval for a further project **before** your existing ethical approval expires to permit the continued storage of that tissue on UWE premises.

Standard disposal options of surplus relevant material is by incineration, cremation or burial. Further details are given in the *UWE Standard Operating Procedure: Disposal of Human Tissue (Relevant Material)*, which can be found at: http://www1.uwe.ac.uk/research/researchgovernance/resourcesforresearchers/humantissueresearch.aspx

18. Serious Adverse Events

A Serious Adverse Event (SAE) is an untoward occurrence that:
(a) results in death
(b) is life-threatening
(c) requires hospitalisation or prolongation of existing hospitalisation
(d) results in persistent or significant disability or incapacity
(e) consists of a congenital anomaly or birth defect
(f) is otherwise considered medically significant by the investigator.

A SAE occurring to a research participant should be reported to the relevant Research Ethics Committees where, in the opinion of the Chief Investigator, the event was related to administration of any of the research procedures, and was an unexpected occurrence.

The SAE must be reported to the Research Ethics Committee that originally approved the application, in addition to the appropriate UWE Research Ethics Committee, as detailed below:

<u>Reporting SAEs to NHS RECs</u>

- All SAEs must also be reported to the UWE Research Ethics Committee that ratified the NHS research ethics applications **prior to** reporting to the NHS REC. This will allow the UWE REC to provide appropriate guidance and support to the UWE Project Manager when reporting an SAE to the NHS REC.

- Reports of SAEs should be provided to the NHS REC that reviewed the application within 15 days of the Chief Investigator becoming aware of the event, in the format prescribed by NRES and published on the website: www.hra.nhs.uk/resources/during-and-after-your-study/progress-and- safety-reporting/

- The Chief Investigator may be requested to attend a meeting of the Committee or Sub-Committee to discuss any concerns about the health or safety of research subjects.

- Reports should only be sent to the NHS REC which reviewed the application.

- You may also need to report the SAE to appropriate NHS Trust R&D Departments that are hosting the research affected by the SAE. Further guidance can be found at: www.hra.nhs.uk/resources/during-and-after-your-study/progress-and- safety-reporting/

Reporting SAEs to other external Research Ethics Committees

- All SAEs must also be reported to the UWE Research Ethics Committee that ratified the external research ethics application **prior to** reporting to the external REC. This will allow the UWE REC to provide appropriate guidance and support to the UWE Project Manager when reporting an SAE to the external REC.

- UWE Project Managers are advised to check the guidance from the external REC that originally approved the application, as there may be a specified time frame in which the SAE must be reported.

Reporting SAEs to the UWE Research Ethics Committee

- Where the research was approved internally by a UWE Research Ethics Committee, then any adverse events which occur as a result of the research should be notified to the UREC/FREC which approved the research, in line with the UWE Policy on Research Ethics: www1.uwe.ac.uk/research/researchethics/policyandprocedures.aspx.

19. UWE Human Tissue Sub-Committee Audit Policy and Guidelines

UWE HTSC audits are being implemented to enable two key objectives:

- To develop and maintain a collaborative working approach relating to human tissue work in the University. Audits will identify good practice that can guide future updates to the UWE HTSC policies and procedures for research with "relevant material" and other projects that involve human tissue but fall outside the remit of the HTA.
- To ensure that all staff working with relevant material maintain on-going compliance with the legislation and the UWE HTSC policy and procedures for work under its remit.

Further details can be found in the UWE *Standard Operating Procedure: Human Tissue Sub-Committee Audit Policy and Guidelines*, which can be found at: http://www1.uwe.ac.uk/research/researchgovernance/resourcesforresearchers/humantissueresearch.aspx

Audit Activity in the Event of Intent to Seek a HT Licence

The requirements for licensing are substantial, and the inspection process of licensed centres is more detailed than the process outlined for UWE at this time. Further details about the HTA 'Inspection Process' for licenced facilities can be found at: www.hta.gov.uk/policies/inspections. Further details are given in Section 20 below.

Therefore if the decision is made to seek a licence, then the audit activity as well as working practice at UWE will need to change and further guidance will then be issued.

20. Licence Quality Standards

UWE does not currently hold a Human Tissue Licence, although the University may consider whether this is appropriate in the future. The standards required for a licence are, however, a measure of good practice, and the University wishes to ensure these standards are in place. This is aspirational, and the University will be working towards implementing the required standards, and researchers are expected to comply with these standards wherever possible. The expected standards are set out at **Annex 5**.

Document Owner: Ros Rouse (Research Governance Manager)

Annex 1

Glossary of Terms

Appropriate consent: Defined in the Human Tissue Act by reference to the person who may give consent. This is broadly either the consent of the person concerned, their nominated representative or (in the absence of either of these) that of a person in a qualifying relationship to them immediately before they died.

Cells: Individual human cells or a collection of human cells when not bound by any form of connective tissue. For establishments licensed for human application this includes cell lines grown outside the human body but not gametes, embryos outside the human body, or blood and blood components.

Primary Cells: Primary human tissue and cells i.e. tissues and cells removed directly from a person are defined as relevant material under the HT Act. Cell lines resulting from expansion of primary cell cultures are not relevant material, as all the original cells have divided and so have been created outside the human body. The storage of cell lines for research does not require an HTA license.

Designated Individual (DI): The individual designated on the licence to supervise the licensable activities being carried out. DIs are trained by the HTA to carry out this important role and they have statutory responsibilities they must fulfil.

Donor: Every human source, whether living or deceased, of tissue, cells, organs or part organs.

Existing holdings: The body of a deceased person, or any relevant material which has come from the human body, held immediately prior to 1 September 2006.

Human Tissue Authority (HTA): The HTA was set up in 2005 as an executive agency of the Department of Health to regulate organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, education and training, and display in public.

Licensing: A number of activities can only be carried out where the establishment is licensed under the Human Tissue Act by the HTA. Organisations whose activities involve the removal, storage or use of relevant material may need to work under an HTA licence. All establishments working under an HTA licence must work to specified standards set by the HTA.

Licensed premises: Where the licensed activity takes place. If the licensed activity will take place at more than one place, a separate licence will be issued for each place. Premises in different streets or with different postal codes are considered as being in different places. In contrast, different buildings on a hospital site could be regarded as the same place.

NHS REC: National Research Ethics Committee (NHS REC) is a committee, constituted of professional and lay members, which reviews applications for research and gives an opinion about the proposed participant involvement and whether the research is ethical. **HRA is** the body to which applications to an NHS REC are made.

Processing: All operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human application.

Relevant material: Defined by the Human Tissue Act as material other than gametes, which consists of, or includes, human cells. In the Human Tissue Act, references to relevant material from a human body do not include: (a) embryos outside the human body, or (b) hair and nail from the body of a living person. See policy guidance on how to apply this definition on the HTA's website:
www.hta.gov.uk/guidance/licensing_guidance/definition_of_relevant_material.cfm

Research: A study which addresses clearly defined questions, aims and objectives in order to discover and interpret new information or reach new understanding of the structure, function and disorders of the human body. Research attempts to derive new knowledge and includes studies that aim to generate hypotheses, as well as studies that aim to test them or develop practical applications of new knowledge.

Recognised Research Ethics Committee:
A Research Ethics Committee (REC) established under and operating to the standards set out in the governance arrangements issued by the UK Health Departments [www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005727]; or an ethics committee recognised by United Kingdom Ethics Committee Authority (UKECA), to review clinical trials of investigational medicinal products under the Medicines for Human Use (Clinical Trials) Regulations 2004 [http://www.legislation.gov.uk/uksi/2004/1031/contents/made].

Tissue: Any and all constituent part/s of the human body formed by cells, or individual cells. See also definition of 'relevant material' below at Annex 3.

UWE Project Manager: The UWE staff member with overall University management responsibility for the project (as defined in the *UWE Code of Good Research Conduct*).

Valid consent: Consent which has been given voluntarily, by an appropriately informed person who has the capacity to agree to the activity in question.

Annex 2

Human Tissue Sub-Committee Terms of Reference

Purpose

To be responsible to the University Research and Knowledge Exchange Committee for the development and implementation of the University's policies and procedures in relation to human tissue research.

Composition

- Member of the University Research and Knowledge Exchange Committee (Chair)- nominated by the Chair of RKE
- Research Governance Manager
- Chair of UREC (or nominee)
- Chair of FREC (or nominee) from any faculty where HT work is undertaken
- Senior Research Laboratory Manager from HAS
- Senior management representative from each faculty where HT work is undertaken –nominated by the Dean
- UG/PG Biological Sciences Research Project Leader (HAS) or nominee
- 4 Senior Researchers engaged in Human Tissue research and teaching – nominated by the Chair
- External Member from UOB
- Co-opted Members as appropriate

- Secretary: RBI

Terms of Reference

1. To exercise, on behalf of the Research and Knowledge Exchange Committee, oversight of the development and implementation of the University's policies and procedures in relation to the storage and use of human tissue for research and teaching purposes.

2. Oversee the annual monitoring of human tissue holdings and their use for research and teaching purposes, in relation to compliance with formal requirements upon the university, including meeting the requirements of the Human Tissue Act.

3. To specify the requirements for, and receive, annual reports from Faculties using Human Tissue research, including the identification of good practice and the promotion of excellence in the use of human tissue within the University, and monitoring of good governance.

4. To receive quarterly updates from Faculties on human tissue use to feed in to the annual monitoring exercise, and provide opportunities for ongoing consideration during the year.

5. Drawing upon the annual monitoring exercise and annual Faculty reports, to report annually to the Research and Knowledge Exchange Board on the implementation of the University's policies and procedures in relation to use of human tissue.

6. To establish a pool of expert advisers to provide advice on the use of human tissue to staff and postgraduate students.

7. To set minimum compulsory training requirements for staff and students in relation to working with human tissue, and to review the implementation of this as part of the annual monitoring exercise.

8. To oversee appropriate records management policy and procedures for work with human tissue.

9. To raise formally with Deans any breaches of compliance or research governance which have come to the Committee's attention.

10 To report formally to the Research and Knowledge Exchange committee any serious concerns which the Committee has been unable to resolve.

11. To promote effective partnerships with external organisations in pursuit of the University's human tissue research and teaching

12. To monitor the policies and practices of key external organisations ensuring that the university is alert to, and responds to, national and international developments in human tissue research and teaching, and to appropriately disseminate this information within the university.

Minimum number of members that must be present to constitute a valid meeting (Quorum):

One-third of the members eligible to attend

Frequency of meetings:

Five per year

For more information please contact:

researchgovernance@uwe.ac.uk.

Annex 3

From HTA Website: Definition of relevant material

This page sets out guidance on the definition of what the Human Tissue Act (2004) refers to as 'relevant material'. This definition excludes human application.
Originally issued 18 December 2008
Reviewed and revised February 2014

The definition of relevant material in the Act is:

Section 53: Relevant material

1. In this Act, "relevant material" means material, other than gametes, which consists of or includes human cells.

2. In this Act, references to relevant material from a human body do not include:

(a) embryos outside the human body, or
(b) hair and nail from the body of a living person.
The Act's use of the words "…or includes human cells" in its explanation of the term suggests that Parliament meant it to be comprehensive. Hansard records a Ministerial statement that the term applied irrespective of the number of cells in the material.

Examples of relevant material
The fundamental concept of relevant material is that if a sample is known to contain even a single cell that has come from a human body, then the sample should be classified as relevant material.

1. Specifically identified relevant material
This includes material such as bodies, organs and tissues, consisting largely or entirely of cells, and clearly identifiable.

2. Processed material
Where a processed material is generally agreed – as a result of the process – to leave it always either cellular or acellular, then the presumption should be that all examples should be regarded as such. The HTA would rely on an assurance that the process in question had been carried out. Under this category, plastinated tissue and plastinated body parts (where the cellular structure is retained by the plastination process) are considered relevant material; while plasma or serum, for example, will not be regarded as such. Plasma and serum, widely produced from blood taken for diagnostic investigations, are however

examples of where 'normal expectations' may well need to be applied. There is more information on this in the HTA's List of materials considered to be 'relevant material' under the Human Tissue Act 2004.

3. Bodily waste products (including excretions and secretions)
The HTA considers bodily waste should normally be regarded as relevant material. The Act's wording is clear and reflects the possibility that even a single cell can be subject to an activity such as research. There will be cases where a person believes that material, intended for a scheduled purpose, is actually acellular. In such cases, the HTA can be approached for advice.

4. Cell deposits and tissue sections on microscope slides
In general, cell deposits or tissue sections on microscope slides are considered to constitute relevant material. This is because such deposits or sections are likely to contain whole cells or are intended to be representative of whole cells.

Lists of materials
To supplement the HTA's information about relevant material, a list has been produced to provide stakeholders with further guidance on whether specific materials fall within the definition of relevant material under the Act.

Please see the List of materials considered to be 'relevant material' under the Human Tissue Act 2004.

Please also see the List of materials under the 2007 Quality and Safety Regulations: https://www.hta.gov.uk/sites/default/files/Supplementary_list_for_HA_Sector.pdf

From HTA Website: **List of materials considered to be 'relevant material' under the Human Tissue Act 2004**

This list is intended to supplement the HTA's guidance on 'relevant material'.

The list is not intended as exhaustive or exclusive, but is intended to provide guidance to stakeholders in respect of a number of materials that might be considered relevant material. The HTA will review the list periodically and update it as required.

Where a material is not included within the following list, stakeholders should use the information on our website to make their own assessment about whether it is relevant material, seeking advice from us where necessary.

Materials classified in the following list as relevant material are done so subject to the following general caveat that they are relevant material except where:

- They have divided or been created outside the human body
- They have been treated, processed or lysed through a process intended to render them acellular. This would include the freezing or thawing of cells only where that process is intended to render the material acellular.

Although cell damage can be minimised by controlling the rate of temperature change and/or by adding one or more 'cryoprotective' agents, freezing/thawing can cause cell damage such that no whole cells remain. Centrifugation can be used to remove residual platelets from plasma, rendering it acellular, but the effectiveness is dependent on the protocol used. In either case, sufficient validation data (either in-house or published research) should be provided if the techniques are to be relied on to render samples acellular.

Antibodies	No	Nail (from deceased person)	Yes
Bile	Yes	Nail (from living person)	No
Blood	Yes	Nasal and bronchial lavage	Yes
Bone marrow	Yes	Non-blood, derived stem cells (i.e. derived from the body.)	Yes
Bones/skeletons	Yes	Non-fetal products of conception (i.e. the amniotic fluid, umbilical cord, placenta and membranes)	Yes
Brain	Yes		
Breast milk	Yes	Organs	Yes
Breath condensates and exhaled gases	No	Pericardial fluid	Yes
Buffy coat layer (interface layer between plasma and blood cells when blood is separated)	Yes	Plasma (Please note: Depending on how plasma is prepared and processed, it may contain small numbers of platelets and other blood cells. If any of these cells are present, then the plasma must be regarded as relevant material).	No
Cell lines	No		
Cells that have divided in culture	No	Platelets	Yes
CSF (cerebrospinal fluid)	Yes	Pleural fluid	Yes
Cystic fluid	Yes	Primary cell cultures (whole explant/biopsy present)	Yes
DNA	No	Pus	Yes
Eggs (ova)*	No	RNA	No
Embryonic stem cells (cells derived from an embryo)	No	Saliva	Yes
Embryos (outside the body)*	No	Serum	No

Extracted material from cells e.g. nucleic acids, cytoplasmic fractions, cell lysates, organelles, proteins, carbohydrates and lipids.	No	Skin	Yes
Faeces	Yes	Sperm cells (spermatozoa)*	No
Fetal tissue	Yes	Sputum (or phlegm)	Yes
Fluid from cystic lesions	Yes	Stomach contents	Yes
Gametes*	No	Sweat	No
Hair (from deceased person)	Yes	Teeth	Yes
Hair (from living person)	No	Tumour tissue samples	Yes
Joint aspirates	Yes	Umbilical cord blood stem cells	Yes
Lysed cells	No	Urine	Yes
Mucus	Yes		

Notes

* While outside the definition of relevant material for the purposes of the Human Tissue Act 2004, these materials fall within the remit of the Human Fertilisation and Embryology Act 1990, and are regulated by the Human Fertilisation and Embryology Authority (HFEA).
Updated May 2014

Annex 4

University of the West of England
BRISTOL

APPLICATION FOR ETHICAL REVIEW OF RESEARCH USING HUMAN TISSUE

Guidance Notes

Please note that UWE does not currently hold an HTA Licence for storage of human tissue.

These notes are intended to be read when completing the application form for ethical review of human tissue research that does not fall within the scope of the Human Tissue Act or does not otherwise require ethical review by an external research ethics committee. You should familiarise yourself with the Human Tissue Authority (HTA) Codes of Practice on Research; Consent; Disposal, Import and Export which can be found at:
www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm

Please ensure that you have considered whether you need approval for your research from a 'recognised Research Ethics Committee' via the IRAS system. If you are uncertain please seek advice from your Departmental Ethics Lead, AHoD RKE or Centre Director in the first instance or contact the Officer of the UWE Human Tissue Sub-Committee researchgovernance@uwe.ac.uk. Guidance may also be sought from the Health Research Authority at: www.hra.nhs.uk.

1. If your research involves NHS patients (including tissue or organs obtained from them), you will need to obtain NHS REC approval.
2. If you intend to collect any relevant material and store it for more than a week then you will need NHS REC approval.
3. If you wish to import relevant material from another country for your research and store it at UWE for more than a week you must apply for ethical review and approval from an NHS REC.

However, if your project:

1. is using material that is acellular when brought on to UWE premises, or
2. is storing samples that will be transported on from UWE premises within one week or rendered acellular within one week, or
3. is storing samples for use in a research project that falls outside of the HTA definition of 'research'
4. **and** there is no other reason that the research must be considered via an NHS REC or another external ethics committee

then you **must** make an application to UWE FREC/UREC for ethical review of the project using this Application Form. Applications made using the standard UWE Ethics Application Form will not be accepted for research projects using human tissue.

Please note that the UWE ethical review process takes **up to six weeks** from receipt of a valid application. **If your project is approved you will need to complete a registration form to register your research on the UWE *Human Tissue Research Register*. The registration form may be**

obtained from the Research Governance Team: researchgovernance@uwe.ac.uk. The research should not commence until you have received your UWE *Human Tissue Research Register* Reference Number. You should bear this in mind when setting a start date for the project.

APPLICANT DETAILS

Name of Applicant			
Faculty		Department	
Status: Staff/PG Student/ MSc Student/ Undergraduate		Email address	
Contact postal address			
Name of co-researchers (where applicable)			

FOR STUDENT APPLICANTS ONLY

Name of Supervisor/Director of Studies	
Detail of course/degree for which research is being undertaken	
Supervisor's/Director of Studies' email address	
Supervisor's/ Director of Studies' comments	***Please note the supervisor must add comments here. Failure to do so will result in the application being returned.***

For student applications, supervisors should ensure that all of the following are satisfied before the study begins:

- The topic merits further research;
- The student has the skills to carry out the research;
- The participant information sheet is appropriate;
- The procedures for recruitment of research participants and obtained informed consent are appropriate.

PROJECT DETAILS

Project title	
Is this project externally funded?	Yes/No
If externally funded	

please give PASS reference			
Proposed project start date		Anticipated project end date	

DETAILS OF THE PROPOSED WORK

Aims, objectives of and background to the research
This should provide the reviewer of the application with sufficient detail to allow them to understand the nature of the project and its rationale, in terms which are clear to a lay reader. Do not assume that the reader knows you or your area of work. You may provide a copy of your research proposal in addition to completing this section.
Research methodology to be used
You should explain how you plan to undertake your research. Include an explanation of why donated human tissue is required for your research and describe any information you intend to collect about the research participants/donors. Where applicable a copy of any interview schedule/ questionnaire/personal data sheet should be attached.
SELECTION OF PARTICIPANTS
You must indicate if any of the participants in your sample group are in the categories listed. Research involving adult participants who might not have the capacity to consent or who fall under the Mental Capacity Act must be reviewed either by an NHS REC or the National Social Care Research Ethics Committee. *If your proposed research involves contact with children or vulnerable adults, or others of the specified categories below, you may need to hold a valid DBS check. Evidence of a DBS check should take the form of an email from the relevant counter signatory confirming the researcher has a valid DBS check for working with children and/or vulnerable adults. It is the responsibility of the applicant to provide this confirmation.* *Members of staff requiring DBS checks should contact Human Resources hr@uwe.ac.uk. DBS checks for students are usually organised through the student's faculty, but students in faculties without a DBS counter signatory should contact Leigh Taylor (Leigh.Taylor@uwe.ac.uk).*
Will the participants be from any of the following groups? *('x' as appropriate)* ☐ Children under 18* ☐ Adults who are unable to consent for themselves ☐ Adults who are unconscious, very severely ill or have a terminal illness ☐ Adults in emergency situations ☐ Adults with mental illness (particularly if detained under Mental Health Legislation) ☐ Prisoners ☐ Young Offenders ☐ Healthy Volunteers (where procedures may be adverse or invasive) ☐ Those who could be considered to have a particularly dependent relationship with the

investigator, e.g. those in care homes, medical students

☐ Other vulnerable groups

☐ None of the above

** If you are researching with children please provide details of completed relevant safeguarding training.*

If any of the above applies, please justify their inclusion in this research.

Please explain how you will determine your sample size/recruitment strategy, and identify, approach and recruit your participants. Please explain arrangements made for participants who may not adequately understand verbal explanations or written information in English

In this section, you should explain the rationale for your sample size and describe how you will identify and approach potential participants and recruit them to your study.

Please describe how you propose to collect, process, store and dispose of the human biological samples

In this section, you should explain what samples will be collected, who will collect them and how they will be collected. Describe the arrangements for processing the samples (e.g. rendering them acellular), storing and disposing of them.

What are your arrangements for obtaining informed consent whether written, verbal or other? (where applicable, copies of participant information sheets and consent forms should be provided)

Informed consent is an ethical requirement of most research. Applicants should demonstrate that they are conversant with and have given due consideration to the need for informed consent and that any consent forms prepared for the study ensure that potential research participants are given sufficient information about a study, in a format they understand, to enable them to exercise their right to make an informed decision whether or not to participate in a research study. You should make clear whether consent being sought is project specific or generic.

Consent must be freely given with sufficient detail to indicate what donating human tissue for the study will involve. Withdrawal from future participation in research is always at the discretion of the participant. There should be no penalty for withdrawing and the participant is not required to provide any reason. You should explain how you will deal with the human tissue samples if the donor wishes to withdraw from the study.

You should describe how you will obtain informed consent from the participants/donors and, where this is written consent, include copies of participant information sheets and consent forms. Where other forms of consent are obtained (e.g. verbal, recorded) you should explain the processes you intend to use. (See also data access, storage and security below).

If the research generates personal data, please describe the arrangements for maintaining anonymity and confidentiality (or the reasons for not doing so)

You should explain what measures you plan to take to ensure that the information provided by research participants is anonymised/pseudonymised (where appropriate) and how it will be kept confidential. In the event that the data are not to be anonymised/pseudonymised, please provide a justification.

Personal data is defined as 'personal information about a living person which is being, or which will be processed as part of a relevant filing system. This personal information includes for example, opinions, photographs and voice recordings' (UWE Data Protection Act 1998, Guidance for Employees).

Please describe how you will store data collected in the course of your research and maintain data security and protection.

Describe how you will store the data, who will have access to it, and what happens to it at the end of the project, including any arrangements for long-term storage of data and potential re-use. If your research is externally funded, the research sponsors may have specific requirements for retention of records. You should consult the terms and conditions of grant awards for details.

***It may be appropriate for the research data to be offered to a data archive for re-use. If this is the case, it is important that consent for this is included in the participant consent form**.*

UWE IT Services provides data protection and encryption facilities - see www.uwe.ac.uk/its-staff/corporate/ourpolicies/intranet/encryption_facilities_provided_by_uwe_itservices.shtml

What risks (e.g. physical, psychological, social, legal or economic), if any, do the participants face in taking part in this research and how will you ADDRESS these risks?

Describe ethical issues related to the physical, psychological and emotional wellbeing of the participants, and what you will do to protect their wellbeing. If you do not envisage there being any risks to the participants, please make it clear that you have considered the possibility and justify your approach.

Are there any potential risks to researchers and any other people impacted by this study as a consequence of undertaking this research that are greater than those encountered in normal day to day life?

Describe any health and safety issues including risks and dangers for both the participants and yourself (if appropriate) and what you will do about them. This might include, for instance, arrangements to ensure that a supervisor or co-researcher has details of your whereabouts and a means of contacting you when you conduct interviews away from your base; or ensuring that a 'chaperone' is available if necessary for one-to-one interviews.
Please check to confirm you have carried out a risk assessment for your research ☐

How will the results of the research be reported and disseminated?

Please indicate in which forms and formats the results of the research will be communicated.

(Select all that apply)

☐ Peer reviewed journal

☐ Conference presentation

☐ Internal report

☐ Dissertation/Thesis

☐ Other publication

☐ Written feedback to research participants

☐ Presentation to participants or relevant community groups

☐ Digital Media

☐ Other (Please specify below)

12. WILL YOUR RESEARCH BE TAKING PLACE OVERSEAS?

If you intend to undertake research overseas, please provide details of additional issues which this may raise, and describe how you will address these. e.g. language, culture, legal framework, insurance, data protection, political climate, health and safety. Please also clarify whether or not ethics approval will be sought locally in another country.

13. Are there any other ethical issues that have not been addressed which you would wish to bring to the attention of the Faculty and/or University Research Ethics Committee?

This gives the researcher the opportunity to raise any other ethical issues considered in planning the research or which the researcher feels need raising with the Committee. This might include a description and explanation of the import or export of samples. Please describe and attach copies of any material transfer agreements.

CHECKLIST

Please complete before submitting the form

	Yes/No
Will all samples be acellular (i.e. not considered relevant material) on arrival at UWE?	
Will any samples considered to be relevant material be transported on from UWE premises within one week, or rendered acellular within one week?	
Will any samples considered to be relevant material be used in research 'in connection with disorders, or the functioning, of the human body'?	
Is a copy of the research proposal attached?	
Have you explained how you will select the participants/donors?	

Have you described how you will collect, process, store and dispose of the human tissue samples?	
Is a participant/donor information sheet attached?	
Is a participant/donor consent form attached?	
Is a copy of your questionnaire/interview or personal data sheet attached?	
Have you described the ethical issues related to the well-being of participants?	
Have you described fully how you will maintain confidentiality?	
Have you included details of data protection including data storage?	
Where applicable, is evidence of a current DBS (formerly CRB) check attached?	
Is a Risk Assessment form attached? (HAS only)	
Have you considered health and safety issues for the participants and researchers?	

DECLARATION

The information contained in this application, including any accompanying information, is to the best of my knowledge, complete and correct. I have attempted to identify all risks related to the research that may arise in conducting this research and acknowledge my obligations and the right of the participants.

Principal Investigator name	
Signature	
Date	
Supervisor or module leader name (where appropriate)	
Signature	
Date	

The signed form should be submitted electronically to Committee Services: researchethics@uwe.ac.uk and email copied to the Supervisor/Director of Studies where applicable together with all supporting documentation (research proposal, participant information sheet, consent form etc.).

For student applications where an electronic signature is not available from the Supervisor we will require an email from the Supervisor confirming support.

Please provide all the information requested and justify where appropriate.

For further guidance, please see www1.uwe.ac.uk/research/researchethics (applicants' information)

Annex 5

Standards that are expected for a Human Tissue Licence in the research sector

Consent standards

C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's Codes of Practice

a) Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.

b) Consent forms are available to those using or releasing relevant material for a scheduled purpose.

c) Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice.

d) Written information is provided to those from whom consent is sought, which reflects the requirements of the HT Act and the HTA's Codes of Practice.
e) Language translations are available when appropriate.

f) Information is available in formats appropriate to the situation.

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent

a) There is suitable training and support of staff involved in seeking consent, which addresses the requirements of the HT Act and the HTA's Codes of Practice.

b) Records demonstrate up-to-date staff training.

c) Competency is assessed and maintained.

Governance and quality systems standards

GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process

a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities

b) There is a document control system.

c) There are change control mechanisms for the implementation of new operational procedures.

d) Matters relating to HTA-licensed activities are discussed at regular governance meetings, involving establishment staff.

e) There is a system for managing complaints.

GQ2 There is a documented system of audit

a) There is a documented schedule of audits covering licensable activities

b) Audit findings include who is responsible for follow-up actions and the timeframes for completing these

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

a) Qualifications of staff and all training are recorded, records showing attendance at training.

b) There are documented induction training programmes for new staff.

c) Training provisions include those for visiting staff.

d) Staff have appraisals and personal development plans.

GQ4 There is a systematic and planned approach to the management of records

a) There are suitable systems for the creation, review, amendment, retention and destruction of records.

b) There are provisions for back-up / recovery in the event of loss of records.

c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).

GQ5 There are systems to ensure that all adverse events are investigated promptly

a) Staff are instructed in how to use incident reporting systems

b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.

GQ5 There are systems to ensure that all adverse events are investigated promptly

a) Staff are instructed in how to use incident reporting systems
b) Effective corrective and preventive actions are taken where necessary and improvements in practice are made.

GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored

a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.

b) Risk assessments are reviewed regularly.

c) Staff can access risk assessments and are made aware of risks during training.

T1 A coding and records system facilitates the traceability of bodies and human tissue, ensuring a robust audit trail

a) There is an identification system which assigns a unique code to each donation and to each of the products associated with it.

b) A register of donated material, and the associated products where relevant, is maintained.

c) An audit trail is maintained, which includes details of: when and where the

bodies or tissue were acquired and received; the consent obtained; all sample storage locations; the uses to which any material was put; when and where the material was transferred, and to whom.

d) A system is in place to ensure that traceability of relevant material is maintained during transport.

e) Records of transportation and delivery are kept.

f) Records of any agreements with courier or transport companies are kept.

g) Records of any agreements with recipients of relevant material are kept.

T2 Bodies and human tissue are disposed of in an appropriate manner

a) Disposal is carried out in accordance with the HTA's Codes of Practice.

b) The date, reason for disposal and the method used are documented.

PFE1 The premises are secure and fit for purpose

a) An assessment of the premises has been carried out to ensure that they are appropriate for the purpose.
b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained

c) There are documented cleaning and decontamination procedures

PFE2 There are appropriate facilities for the storage of bodies and human tissue

a) There is sufficient storage capacity.

b) Where relevant, storage arrangements ensure the dignity of the deceased.

c) Storage conditions are monitored, recorded and acted on when required.

d) There are documented contingency plans in place in case of failure in storage area.

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored

a) Equipment is subject to recommended calibration, validation, maintenance, monitoring, and records are kept.

b) Users have access to instructions for equipment and are aware of how to report an equipment problem.

c) Staff are provided with suitable personal protective equipment.

Document Owner: Ros Rouse (Research Governance Manager)

Annex 6

UWE Human Tissue cover letter for onward transport/return of samples

[NAME]
[ADDRESS]

[DATE]

Dear [NAME],

Re: [REFERENCE NUMBER/IDENTIFYING INFORMATION]

[NUMBER OF] samples of [DESCRIPTION OF TISSUE] are being [BASIS UPON WHICH THE SAMPLES ARE BEING PASSED ON, E.G. RETURNED TO YOU AS OWNER; PROVIDED IN COLLABORATION WITH PROJECT UNDER REF NUMBER XX; ETC.].

As arranged this will be delivered by registered post on [DATE OF DELIVERY] to [YOU/YOUR NOMINATED REPRESENTATIVE] following [YOUR/THEIR] agreement that [YOU/THEY] will be in a position to accept them.

In accordance with the Human Tissue Act (2004) the complete ledger will accompany the samples. Please check the delivery against the ledger as soon as the samples have been received and email me to confirm that all samples are present and correct.

Yours sincerely,

Annex 7

Approvals needed for Human Tissue research at UWE

Approvals needed **Type of research**	NHS Research Ethics Committee (NREC)	Other external REC	UWE HT Ethics (UREC/FREC)	UWE general ethics (UREC/FREC)	UWE Ethics ratification	UWE HT Register
Research using relevant human tissue which falls under the definition of research or other scheduled purpose (as defined by the HT Act).	✓	✗	✗	✗	✓	✓
Research using relevant human tissue which does not fall under the definition of research or other scheduled purpose (as defined by the HT Act).	✗	✗	✓	✗	✗	✓
Research involving primary cells lines (not including commercial cells lines)	✓ (a)	✗	✗	✗	✓	✓
Research using non-relevant (as defined by the HTA) and non-identifiable human tissue, purchased commercially and without involvement of human participants.	✗	✗	✗	✗	✗	✓
Research using non-relevant (as defined by the HTA) human tissue **and/or** research which does not fall under the definition of research or other scheduled purpose (as defined by the HT Act), **BUT** which involves human participants.	✗	✗	✗	✓	✗	✓
DNA research where non-identifiable cellular material from the living is stored with the intention of conducting DNA analysis **without consent**	✓	✗	✗	✗	✓	✓

DNA research with tissue from the living and consent for the **specific** study	✗	✗	✓	✗	✗	✓
Storage of human tissue for research purposes (as defined by the HT Act).	✓	✗	✗	✗	✓	✓
Storage of human tissue that will be transported on or rendered acellular within one week **prior to the commencement of the research**	✗	✗	✓	✗	✗	✓
Human Tissue which is cellular when brought on to site and the research commences **before the cells are rendered acellular** (even if the course of the research would cause the cells to be rendered acellular within a week of arrival),	✓	✗	✗	✗	✓	✓
Type of research						
Research using human tissue from a UK tissue bank with **existing NREC approval**	✓ (b)	✗	✗	✗	✓	✓
Research where a 'finger prick' test is taken, and used immediately and then immediately disposed of (autoclaved within five days at the absolute maximum).	✗	✗	✓	✗	✗	✓
Research involving human tissue from the body of a person who died before Section 16 of the Human Tissue Act 2004 came into force **and** at least 100 years have elapsed since the date of the person's death.	✗	✗	✓	✗	✗	✓
UWE Researchers working with HTA relevant materials not on UWE **OR** NHS premises	✗	✓ (c)	✗	✗	✓	✓
UWE researchers working overseas	✗	✓ (d)	✗	✗	✓	✓

UWE researchers importing tissue from overseas	✓	✓ (e)	✗	✗	✓	
Research involves NHS patients (including tissue or organs obtained from them)	✓	✗	✗	✗	✓	✓
Research involving gametes and embryos	✗	✓ (f)	✗	✗	✓	✓

(a) NREC approval must have been in place at the time the cells were collected and provided to UREC/FREC for ratification
(b) Existing REC approval should be provided to UREC/FREC – new NREC approval not required.
(c) A formal agreement between UWE and the site where tissue is being accessed is required
(d) A favourable ethical opinion must be in place to cover the specific use by the UWE researcher, and UREC/FREC must see adequate evidence of this.
(e) NREC must be made aware of imported tissue and may require an amendment – discuss with REC manager
(f) Research licence required from the Human Fertilisation and Embryology Authority (HFEA)