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Human Samples in Research

Obtaining Informed Consent

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AUTHOR	**Name and role**	Dr Lisa Wakeman HTA Governance Officer	
	Signature and date	Signed copy held in ABM UHB R&D Office	
APPROVER	**Name and role**	Professor Catherine Thornton Designated Individual	
	Signature and date	Signed copy held in ABM UHB R&D Office	
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1. Purpose

The purpose of this standard operating procedure (SOP) is to ensure that all individuals working with human tissue understand the requirements and procedures under the Human Tissue Act 2004 (HT Act) for obtaining consent for the storage of relevant material for the scheduled purpose of research in connection with disorders, or the functioning, of the human body. It is good practice to seek consent in advance of any proposed procedure.

2. Background

This SOP forms part of the joint Swansea University/Abertawe Bro Morgannwg University Health Board (ABM UHB) Quality Management System (QMS) for the governance of the acquisition, storage, use and disposal of human tissue in line with the requirements of the HT Act and the standards set out by the Human Tissue Authority (HTA).

Consent is a fundamental principle of the HT Act and relates to the purposes for which material might be removed, stored or used. These purposes are set out in Schedule 1 of the HT Act and are called 'scheduled purposes'. The issues of consent that are central to the consent provisions of the HT Act are:

- Whether consent is required
- Appropriate consent
- Valid consent
- Scope of consent
- Duration of consent
- Withdrawal of consent

Broadly, the HT Act and HTA codes of practice stipulate that consent is legally required to undertake the following:

- Store and use dead bodies
- Remove, store and use relevant material from a dead body
- Store and use relevant material from the living

Any individuals involved in seeking and receiving consent for the use of human tissue for research purposes must receive training to do so as stipulated in the HTA Code of Practice on consent. The HT Act defines both 'relevant material and 'bodily material'

- Relevant material – Any material removed from the body that consists of or includes human cells. The HT Act definition of relevant material from a human body does not include:

- Gametes
- Embryos outside the human body
- Hair and nails from the body of a living person
- Cell lines or any other human material created outside the human body
- Serum, cell free plasma, DNA and RNA

- Bodily material – Any material from the body of the living or deceased, including gametes, hair and nails.

Individuals involved in removal, storage or use of material in circumstances for which the HT Act requires consent must be satisfied that consent is in place and have full knowledge and understanding of the research including possible sensitive or future use of the tissue. All individuals should be aware of the risks associated with collection and use of the material for research.

Clinicians responsible for dealing with consent and capacity issues in research must practice within the *UK policy framework for health and social care research (2017)* and follow the Research Governance Policy of their substantive employer and the establishment from where the tissue is collected.

Consent to treatment and examination is covered by the common law and Mental Capacity Act (MC Act) 2005. Researchers should refer to the legal position as set out in Department of Health and Welsh Assembly guidance.

3. Roles and Responsibilities

This SOP applies to all Swansea University and ABM UHB staff and students who collect, use or store human tissue for the purpose of research in connection with disorders, or the functioning, of the human body.

It is the responsibility of the Designated Individual (DI) to ensure that consent procedures and practices are appropriate, implemented and adhered to. The DI holds the responsibility of ensuring that those involved in human tissue research under a HTA licence are trained and that the conditions of the licence in relation to research are complied with.

The HTA Governance Officer is responsible for ensuring that the SOP remains fit for purpose.

4. Procedure/Principles

4.1 Consent Requirements

The HT Act makes consent an underpinning principle for research. The HTA Code of Practice on consent sets out the requirements for seeking consent for the use of

tissue from the living and deceased. Different consent requirements apply when seeking and obtaining consent for the use and storage of tissue from the living and tissue from the deceased.

Under the HT Act, consent is always required for the removal, use and storage of material from the deceased for 'research in connection with disorders, or the functioning, of the human body'. The consent given must be appropriate and valid. Consent exemptions exist for the use and storage of human tissue from the living in some circumstances. All University and Health Board researchers should be aware of additional legal requirements such as the data protection legislation and the common law duty of confidentiality.

4.2 Appropriate Consent

The HT Act defines appropriate consent in terms of the person who may give consent. This is either the person concerned i.e. the donor, their nominated representative (if available) or a person in a 'qualifying relationship' with the donor immediately before they die. More information is provided in section 4.11.

4.3 Valid Consent

The giving of consent is a positive act. For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to agree to the activity in question. In research, this means that for the consent to be valid in the context of the HT Act, the person must understand the activity, what it involves and the risks.

Consent is only considered valid if proper communication has taken place. Consideration should be given to the needs of individuals and families whose first language is not English. Records should be kept of any particular communication difficulties encountered and how they were overcome (e.g. use of translator, pictorial representations). Individuals seeking consent should be experienced and trained and ensure that the consent obtained is appropriate for the intended purpose and scope of use.

If identifiable tissue is to be used, the donor should be informed of any implications this may have (e.g. future contact by researchers, feedback). Within the consent process, donors should be asked to specify whether their consent is generic (i.e. for use in any future project) or specific to the individual study. If consent is specific, the donor should be informed of detailed information about the specific study.

The HTA encourages the seeking of informed and generic consent at the outset as the preferred position to facilitate the use of samples for different ethically approved research projects. If the intention is to store the tissue for as yet unspecified research or as part of a research tissue bank, this should be explained, setting out the types of

research that it may be used for, any wider or sensitive implications (e.g. genetic testing, animal research, commercial research, overseas research).

Researchers should give consideration to how tissues will be handled in the event that a participant loses capacity during a study.

4.4 Scope of Consent

Under the HT Act the scope of consent may be specific or generic. Specific consent imposes limitations on the use of the tissue for research. Generic consent typically only applies to research and involves obtaining consent to a broad remit of research allowing the tissues to be used for more than one research project. It is considered good practice by the HTA to obtain generic consent to avoid the necessity to obtain further consent in the future. Consent must still be valid whether specific or generic.

4.5 Duration of Consent

Consent may be enduring or time-limited. Enduring consent remains in force unless consent is withdrawn. A person may prefer to specify a time limit for the period they wish their consent to remain in force. Whether the consent is specific or enduring, the decision should be clearly documented in the donor's records or laboratory or both.

4.6 Withdrawal of Consent

Consent may be withdrawn by an individual at any time, whether it is specific or generic.

Withdrawal of consent should be discussed at the point when consent is sought. The practicalities and implications of withdrawing consent should be discussed with research participants at the outset. Those giving consent should be informed of the limitations of withdrawing consent in the event that samples have already been used.

Individuals giving consent for more than one scheduled purpose may withdraw consent for a particular scheduled purpose, however this does not mean that the samples have to be removed or disposed of unless stored for the particular purpose for which consent was withdrawn. Withdrawal of consent for future research projects does not mean that information or data should be removed from existing projects where consent remains.

Individuals approached for consent should feel at liberty to decline, this decision should be respected and the refusal to participate documented in the patient notes, laboratory records or both as appropriate.

4.7 Consent exemptions

The HTA have stipulated exceptions to the requirement to seek consent for the use of human tissue for the scheduled purpose of research. However, the HTA Code of Practice on consent advocates the seeking of consent in all research as good practice.

In circumstances where relevant material is exempt from the consent provisions of the HT Act, it must still be stored on HTA licensed premises when retained for unspecified future research.

4.7.1 Existing holdings

It is not legally necessary to obtain consent to store or use an existing holding for research. An existing holding is defined as material from the living or deceased that was already held at the time the HT Act came into force on September 1st 2006.

Existing holdings cannot however be used freely and without regard to issues of consent or other ethical considerations. Where practical, the consent of the participant should be obtained retrospectively and where the wishes of the deceased or their relatives exist, these should be observed and respected. Consideration should be given to:

- whether obtaining retrospective consent would cause undue distress
- whether alternative tissues can be used for the research in question
- whether the benefits of the research outweigh any potential harm to the donors of the samples

4.7.2 Samples over 100 years old

If more than 100 years has elapsed since the date of death, consent to undertake research is not required under the HT Act.

4.7.3 Imported Material

Consent for the use of imported material is not required under the HT Act. However, the HTA consider it good practice to implement mechanisms to provide assurance that the tissue has been obtained with valid consent. Imported samples are not exempt from HTA licensing requirements for storage or from the requirement to obtain ethical approval for their use in research. Human tissue must not be exported with the intention of re-importing as a mechanism of avoiding the requirement for consent.

4.7.4 HRA REC Approved and Anonymised Samples from the Living

Relevant material and DNA can be used for research without consent where all of the following apply:

- when collected, the material came from a living person
- the material is anonymised
- the material is used for a specific research project approved by a HRA REC or a Committee recognized by the UK Ethics Committee Authority.

NOTE: Review by University Ethics Committees does not constitute a recognised review committee under this exception. Approval must be obtained from a HRA Research Ethics Committee (REC).

Anonymisation means that the donor is unidentifiable to the researcher. This may be achieved by a robust coding system where samples are uniquely identified. The links between donor information and tissue should be kept securely and under appropriate guardianship. Where a clinician is involved in research and has access to an identifying database of patient material used in that research, the view of the HTA is that it shall be considered as anonymised tissue where the tissue is not identifiable and the researcher does not seek to link the patient and the sample. In this circumstance, where the research has been approved by a recognized REC the consent exception will apply.

4.8 DNA Theft

Consent is required for the storage of DNA and use of the results of DNA analysis in research unless an exemption applies (material is from the living, anonymised and approved by a HRA REC).

An offence will be committed where bodily material (including gametes and hair and nails from the deceased) is held with the intention to analyse DNA for research without consent for non-excepted purposes.

4.9 Seeking Consent and Consent Training

In an NHS setting it is the treating clinician's responsibility to seek consent from a person, person with parental responsibility or relative. The clinician may delegate this task to someone else, usually another healthcare professional, as long as that person is suitably trained and qualified. In particular, they must know enough about the proposed treatment, the intended use of the tissue and the risks involved to adequately brief the person.

Under the HT Act, any individual seeking consent for the removal, storage or use of relevant material for a scheduled purpose must be trained in the process of obtaining

consent. Researchers collecting human material should also be trained in Good Clinical Practice (GCP) and those dealing with friends or relatives of the deceased should have bereavement training. Training on obtaining consent is covered in both the Valid Informed Consent and GCP training courses provided by Health and Care Research Wales. Completion of either course would be considered to be sufficient evidence of receipt of training. A record of attendance should be maintained by the individual and the research project principal investigator. Training records for obtaining consent should be available for internal audit by the DI, HTA Governance Officer and PDs and for external inspection by the HTA.

Seeking and obtaining consent is a sensitive issue therefore researchers and clinicians involved in obtaining consent should be trained in the process. They should be aware of the procedures involved in the proposed research and should be appraised of, and able to discuss, the possible risks and benefits to participants. Sufficient time should be allowed for potential participants to ask questions and engage in discussion if they wish. The input of friends and family members should be encouraged if appropriate.

Under the HT Act, consent is required for the removal, storage and use of human material from the deceased and for storage and use from the living. Removal of tissue from the living is covered by common law.

Procedures should be in place to detail the responsibilities of all those involved in seeking valid consent. Established procedures should be subject to periodic review to ensure they meet the HTA Code of Practice A on consent.

A template consent form, *HTA-02-TEMPLATE-Consent form* is available for adaptation in specific research projects.

4.10 Records of Consent

Researchers who are not directly involved in seeking consent must satisfy themselves that consent has been obtained. This may be evidenced by a letter or alternative documentation from the clinician, tissue bank or relevant organization supplying the tissues and responsible for obtaining consent.

Storage of consent records must be appropriate to the requirements for confidentiality, data protection and security. Records of consent should be kept onsite where possible, these would include:

- signed consent form
- associated information sheet
- records of consent training

If consent records are stored at a location remote from the tissue, details of a named contact at the establishment, a blank consent form and information sheet must be held with the tissue records.

If the material is imported, assurance of valid consent and evidence of appropriate ethical review from the source location must be in place. These may be set out in a material transfer agreement (MTA).

Record keeping and document disposal should be undertaken in accordance with the Swansea University/ABM UHB HTA Standard Operating Procedure *HTA-07-SOP-Management of Records*.

4.11 Who can give consent for storage and use of relevant material?

4.11.1 Human Samples from the Living

- Competent adults

If an adult is competent i.e. has the capacity to make a decision, only they are permitted to give consent.

- Adults lacking capacity

Guidance on research involving participants who lack capacity can be found in the Mental Capacity Act 2005 (MC Act) Code of Practice.

Researchers are legally required to have regard to the MC Act Code of Practice when carrying out research approved in accordance with the act. Researchers should assume a person has capacity, unless there is proof that they lack capacity to make a specific decision. An individual whose capacity is in question has the right to make decisions that may be considered unwise and have the right to refuse to participate in research.

Under the MC Act, a person aged 16 or over is unable to make a decision if they are unable to demonstrate that they can:

  - understand the information given to them, relevant to the decision
  - retain that information long enough to make the decision
  - use or weigh up the information as part of the decision-making process
  - communicate their decision by any means

Where there is doubt about whether an adult has the capacity to provide consent, they should receive help and support to make their own decisions before the conclusion that they cannot do so is reached. Some people may require help to communicate a decision; this does not necessarily mean that they lack capacity to do so. Anybody

who claims that an individual lacks capacity should be able to provide proof. Researchers seeking consent from patients whose capacity is in question must be aware of their own limits of practice and seek opinion and advice elsewhere as necessary.

Exemptions to consent stated in section 4.7.4 of this SOP where tissue is from the living, anonymised and used in ethically approved research (by a recognized committee) apply to adults with and without capacity. Research involving anonymised data is also exempt from consent for persons lacking capacity. Exemptions for research involving human tissue considered to be an existing holding applies to the use of material from individuals lacking capacity.

Researchers and recognized RECs both carry a responsibility for compliance with the MC Act's requirements. REC in this regard refers to HRA RECs or a Committee recognized by the UK Ethics Committee Authority.

Research covered by the MC Act involving people who lack capacity to consent can only proceed where it has the approval of an HRA REC or a Committee recognized by the UK Ethics Committee Authority

Where lack of capacity is temporary such as where the person is unconscious, full consent must be sought as soon as capacity is regained.

- Children

The HT Act defines children as being under 18 years old. Children may consent to the use and storage of their tissue if they are deemed to have sufficient intelligence and understanding to enable them to fully comprehend what is involved. Consent to a procedure by a child carries over into adulthood unless they withdraw it.

- Healthy Volunteers

The general principles of valid consent should be followed when collecting, storing or using relevant material (i.e. any sample that contains even a single cell) from individuals who are not patients. Such individuals should be fully informed of the possible risks in the collection of samples and the uses of their tissue (e.g. genetic tests).

4.11.2 Human Samples from the Deceased

- Adults

Where a living adult has given valid consent before death for any particular removal, storage or use of their body or tissue for research to take place after their death; that consent is sufficient to legally allow the activity to proceed. Should individuals who are

close to the deceased at the time of death object to the consented activity, the matter should be discussed sensitively with them and they should be encouraged to accept their wishes. It should be made clear that they do not have a legal right to veto the wishes of the deceased. Where conflict exists all parties should be engaged in sensitive discussion and the impact of going ahead despite strong feelings of individuals close to the deceased should be considered.

- Nominated Representatives

An individual may, before death, nominate a person to take decisions regarding the removal storage or use of their body or tissues for research. If a deceased adult has not given consent or specific refusal before death, the individuals close to that person should be asked whether a nominated person was appointed to make those decisions. The nomination of such a representative can be made, and revoked, in writing or orally as set out in the HT Act. The decision of a nominated representative cannot be overruled by other individuals including family members.

A nominated representative may not make decisions regarding anatomical examination or public display of relevant material.

- Qualifying Relationships

If the deceased has not indicated consent or refusal for the use or storage of their tissue for research, and a nominated individual has not been appointed or is unavailable or unable to make a decision, then the appropriate consent may be given by someone who was in a qualifying relationship immediately before death. The qualifying relationship hierarchy (highest first) is defined in the HT Act:

1. Spouse or partner (including same sex or civil partner who live as partners in an enduring family relationship)
2. Parent or child (biological or adopted) of any age but must be competent if under 18
3. Brother or sister
4. Grandparent or grandchild
5. Niece or nephew
6. Stepfather or stepmother
7. Half-brother or half-sister
8. Friend of long standing

Consent is only required from one person in the hierarchy and should be obtained from the highest ranking person. If a person higher up the list refuses consent it is not possible to act on consent from an individual further down the list.

- Children

The HT Act defines children as being under 18 years of age. The consent of child who gave consent for the use of their body or tissue for research whilst alive and competent to do so is lawful for the removal, storage or use of tissue for that purpose.

If a child did not give consent or refusal for the removal, storage or use of their tissue for research, the consent of one person with parental responsibility is sufficient.

Children cannot appoint a nominated representative; therefore in the absence of consent or refusal by the child or a person with parental responsibility, consent should be sought from the highest ranking individual in a qualifying relationship with a child.

4.11.3 Foetal Tissue

The law does not distinguish between foetal tissue and tissue from the living and is therefore subject to the same consent requirements as all other tissue from the living. Consent for the removal, storage or use of foetal tissue for research should be obtained from the mother for the examination, storage and use of foetal tissue and non-foetal products of conception (i.e. placenta, membranes, umbilical cord, amniotic fluid), even where the tissue is unidentifiable.

Consent should be in line with that required for the deceased for the use of foetal tissue for research from:

- stillbirths (babies born dead after 24 weeks of gestation)
- neonatal deaths (babies or foetuses born showing signs of life and die before the age of 28 days)

4.11.4 Images of Human Samples

The making and displaying of images (including photographs, films and electronic images) is not covered by the HT Act. However, the HTA expect the Designated Individual to put into place systems that ensure that suitable practices are carried out, including the prevention of inappropriate use of images. The HTA endorses guidance provided by the General Medical Council in its publication *Making and using visual and audio recordings of patients.*

http://www.gmc-uk.org/guidance/ethical_guidance/making_audiovisual.asp

4.12 Participant Information Sheets

Information should be provided to the participant in writing so they can refer back to it, the person seeking consent should also discuss the information sheet with the

participant to ensure the consent is fully informed and that the participant has had the opportunity to ask any questions.

The level of detail contained within the information sheet should be proportional to the research activity, however all information sheets should use simple, non-technical terms that a lay person would easily understand.

When collecting relevant material for use in research, the information sheet must contain the following information:

- Type of tissue to be collected, how much and by which method.
- Whether any identifying information will be affixed to the sample or if the samples will be anonymised / link-anonymised.
- What the material will be used for in the study.
- Whether any genetic testing will be carried out on the material.
- Whether the material will be exported.
- What will happen to the material at the end of the study, e.g. disposed of or retained for future use.
- If consent is being sought for future use of the samples the scope of the future use (who can access it, from where and for what type of research).
- What will happen to the material if consent is withdrawn.

4.12.1 Format of Information Sheets

The Health Research Authority (HRA) has provided guidance on information sheets and consent forms and, although aimed at projects seeking HRA REC approval, the format should be adopted for all studies involving human tissue. Further information on the content of information sheets can be found on the HRA website:

http://www.hra.nhs.uk/research-community/before-you-apply/participant-information-sheets-and-informed-consent/

Where the first language of the potential participant is not English, or where barriers to communication exist, the information sheet should be available in a suitable format (e.g. various languages, Braille) and/or an interpreter should be provided. In Wales both English and Welsh versions of information sheets should be available by law.

4.12.2 Consent Form

The consent form should comprise basic information for the researcher, statements for the donor to initial, demonstrating understanding/agreement, and dated signatures of both donor and researcher. For NHS patients, the original consent form should be kept with the patient's medical notes and two copies made; one for the patient and one to be retained by the researcher. For some studies a fuller, itemised or hierarchical consent form may be needed to cover important issues, especially if additional elements are optional for the participant.

4.12.3 Basic Information

Basic information is usually displayed at the top of the consent form and should typically include:

- study number
- title of project
- name of researcher
- donor ID number
- contact details

4.12.4 Statements of Consent

Boxes for the donor's initials are located alongside written statements to encourage the donor to read each statement individually and facilitate a clear understanding of exactly what they are consenting to. They also allow the donor to consent to certain aspects of the study and not others if that is their choosing.

Mandatory statements need to appear on all consent forms, with additional statements to be included where necessary.

Mandatory statements ensure the donor:

- Confirms that they have read and understood the information sheet and that the patient/participant has had the opportunity to ask questions and these have been answered satisfactorily.

- Understands that participation is voluntary and they are free to withdraw at any time without giving a reason and, if applicable, without their medical care or legal rights being affected.

- Understands what samples will be collected and what will happen to their samples at the end of the study.

- Understands that their medical notes may be accessed by individuals associated with the project (if applicable).
- Agrees to their GP being informed of their participation in the study (if applicable).
- Agrees to take part in the study.

Additional statements will relate to the specific project and might include:

- Additional invasive tests or samples required for study purposes only
- The scope of the future use of samples
- Consent to use of audio/video-taping, with possible use of verbatim quotation or use of photographs
- Export of samples to countries outside England, Wales and Northern Ireland
- Transfer of data/samples to countries with less data protection
- Consent to receive individual feedback from testing
- Consent to being contacted for future studies
- Consent for their DNA to be extracted and analysed
- Consent for sample storage for genetic testing
- Consent for use in humans
- Consent for use in animal testing
- Consent for use in commercial research
- 'Given as gift' - Some RECs have insisted on including a statement confirming that the tissue had been given as a gift and the donor would have no right to a share of any profits that might arise from research using it (e.g. as part of a new medical treatment or test)

4.12.5 Signatures

The signatories to consent should be those who are involved in the consent process, e.g. the participant or representative for the participant and the researcher or a representative of the researcher delegated to take consent. An independent witness is not routinely required but may prove useful in the case of consent by a participant who may are unable to sign personally.

4.12.6 Data Protection Act 1998

Any health related records that identify the living individual who is the source of the tissue sample may constitute that individual's sensitive personal data and as such the Data Protection Act 1998 will require that consent is sought for the processing of such data.

5. Process of Consent

5.1 Existing Holdings (collected before 1st September 2006)

The HT Act indicates that existing holdings are exempt from its consent provisions. An existing holding is defined as the body of a deceased person or relevant material from a human body (whether living or dead) held before the day on which the HT Act commenced (1 September 2006) for use for a Scheduled Purpose.

The following steps should be taken and documented for the use for research purposes of existing holdings.

1) Obtain HRA REC approval for the proposed research project.

2) Ensure full traceability records are maintained with the original study. Evidence should be available detailing:

   - To whom the material was released, when and for what study
   - Ethical approval of the new study
   - Whether the material was released anonymously

3) Ensure full traceability records are maintained with the new study detailing:

   - Where the material was supplied from
   - Date of receipt of the material
   - Ethical approval of the new study
   - Details of the unique sample identification numbers/codes for the original and new studies

5.2 Material collected after 1st September 2006

The following steps should be taken and documented as appropriate, for the re-use of relevant material collected after September 1st 2006 for research.

1) Establish whether the new study is in line with the original donor consent:

   a. If the new study is considered to be in line with the original consent the material could be used without further ethical approval. Details of the new study must be kept with the original traceability records to demonstrate that use was within the scope of the consent. Tissue must be supplied anonymously.

   b. If the new study is considered not to be in line with the original consent and the material was collected from the living, either:

      i. HRA REC approval can be obtained to use the tissue without consent – tissue must be supplied anonymously.

      Or

      ii. Contact the donors for further consent – tissue must be supplied anonymously.

   c. If the new study is not considered to be in line with the original donor consent and the material was collected from the deceased, the material must NOT be used without further consent from the relatives. The person's relatives must not be contacted unless they gave consent for contact or with HRA REC approval to contact them. Approval should be in place before any relatives are contacted.

2) Ensure full traceability with the original tissue collection to evidence:

   a. To whom the material was released, when and for what study

   b. Evidence that the new study was within the scope of the original consent or that HRA REC approval has been obtained for the use of the material without consent (samples from living) or further relative consent (samples from deceased).

3) Ensure full traceability records are maintained with the new study to evidence

   a. from where the material was supplied

b. date of receipt of the material

c. a copy of the original information sheet, blank consent form and HRA REC ethical approval letter.

d. details of the unique sample identification numbers/codes for the original and new studies

e. that the new study is within the scope of the original consent or of HRA REC approval to use the material without consent (samples from living) or further consent from relatives (samples from deceased).

5.3 New Tissue Collections

The consent requirements for collecting tissue for new research projects should be in line with the following steps:

1) Prepare draft information sheets based on guidance produced by HRA as referenced in 4.12.1.

2) Obtain appropriate ethical approval or obtain evidence of approval where relevant material is obtained from a biobank.

3) Ensure that all members of the research team have been trained in obtaining informed consent under the HT Act and that the training is documented.

4) Ensure all members of the research team have a good understanding of the study and that it is documented.

5) When recruiting participants, engage each person in a comprehensive discussion of the research including risks, benefits and be prepared to provide answers to questions.

6) Once consent has been obtained, sample collection, labeling, storage and disposal must take place as documented in the study protocol. HTA standards for consent (Appendix B) should be adhered to throughout these activities.

7) If consent is in place for future tissue use, ensure that the scope and any restrictions on the use are documented and retained with the material.

8) If the tissue is subsequently used for future research, ensure that:

   a. The tissue use in line with the donor consent.
   b. A record is kept of the recipient, date of handover and name of study.

c. Evidence is in place that the future study falls within the scope of the original consent or that ethical approval has been granted to use the material without consent (material from living) or further consent of relatives (material from deceased).

9) If consent is withdrawn, follow the withdrawal protocol in the patient information sheet and ensure that all remaining identifiable tissue is disposed of appropriately in line with local policies.

10) Maintain records of:

a. consent training
b. consent form location
c. ethical approval
d. tissue traceability records
e. other associated records

6. Transportation of Human Tissue

When relevant material is transferred into or out of the University and Health Board this should form part of the information imparted to donors and the transportation activities should be included in the REC submission and be covered by approval. Where relevant material is exported to a country outside of England, Wales or Northern Ireland, the consent of the donor for export of their tissue should be obtained. Please refer *to HTA-06-SOP-Import and Export* for further guidance.

7. References

HTA Code of Practice A: Guiding Principles and the Fundamental Principle of Consent

https://www.hta.gov.uk/sites/default/files/files/HTA%20Code%20A.pdf

Governance Arrangements for Research Ethics Committees: A Harmonised Edition. Department of Health May 2011

Human Tissue Act 2004

Mental Capacity Act 2005

UK policy framework for health and social care 2017

8. Risk Assessment

A risk assessment for this HTA governance SOP is not required.

9 Definitions

Anatomical Examination – An examination, by dissection, of the body of a deceased person for the purpose of teaching or research.

Capacity – The ability to use information to make a decision.

Chief Investigator (CI) – The individual who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves researchers at more than one site, the Chief Investigator takes responsibility for the design, management and reporting of the study, co-ordinating the investigators who take the lead at each site.

Consent - Process by which an individual confirms his/her willingness to participate in a particular procedure. The individual must have been informed of all aspects of the procedure/request that are relevant to the decision to participate. The individual must be competent to take the particular decision, be acting voluntarily and not be acting under duress.

Designated Individual – The person who is authorised and who supervises activities under a licence issued by the Human Tissue Authority.

Human Tissue – Any and all constituent parts of the human body formed by cells.

Human Tissue Act 2004 - Legislation that regulates the removal, storage and use of human tissue, defined as material that has come from a human body and consists of, or includes, human cells. The HT Act covers England, Wales and Northern Ireland. Consent is the fundamental principle of the legislation and underpins the lawful removal, storage and use of body parts, organs and tissue. Different consent requirements apply when dealing with tissue from the deceased and the living. The Human Tissue Act lists the purposes for which consent are required (Scheduled Purposes).

Human Tissue Authority – The independent regulator established by the HT Act to protect public confidence by ensuring human tissue is used safely and ethically, and with proper consent. The HTA licenses and inspects organisations that collect, store and use human tissue for the Scheduled Purposes, for which appropriate consent is required (unless exemptions apply).

HTA Codes of Practice - Provide guidance and lay down expected standards for each of the sectors regulated by the HTA (e.g. research) and under the HT Act. They are designed to support professionals by giving advice and guidance based on real-life experience.

HTA Standards - Core standards in four key areas that must be met for an organisation to obtain an HTA licence, relating to the provisions in the HT Act and the regulatory requirements: Consent; Governance and Quality Systems; Premises, Facilities and Equipment; Disposal.

Research Ethics Service – A core function of the Health Research Authority (HRA). It provides an efficient and robust ethics review service to protect the rights, safety, dignity and well-being of research participants.

Principal Investigator – A Principal Investigator is the primary individual responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, training or public service project, contract, or other sponsored project in compliance with applicable laws and regulations and institutional policy governing the conduct of sponsored research.

Quality Management System - Centralised governance framework policies, procedures, training, provision of advice and guidance, documentation and data records relating to all aspects of acquisition, storage, use and disposal of human samples.

Relevant Material – Any material, other than gametes, removed from the body which consists of or includes human cells. In the HT Act references to relevant material from a human body do not include:

- embryos outside the human body
- hair and nail from the body of a living person
- cell lines or any other human material created outside the human body
- serum, plasma, DNA and RNA

Research - A study that 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.

Scheduled Purposes - The activities relating to the removal, storage and use of human organs and other tissue that require consent, listed in Schedule 1 of the HT Act, e.g. research in connection with disorders or the functioning of the human body.

Standard Operating Procedure – Detailed, written instructions to achieve uniformity of the performance of a specific function which an integral part of a quality management system. In the context of research using human samples, SOPs document all the processes that affect the quality and safety of those samples (e.g. acquisition, storage, transfer and disposal).

Storage – Maintaining the tissue under appropriate controlled conditions.

Appendix B – Human Tissue Authority Standards for Consent

C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice

- Consent procedures are documented and these, along with any associated documents, comply with the HT Act and the HTA's Codes of Practice.
- Consent forms are available to those using or releasing relevant material for a scheduled purpose
- Where applicable, there are agreements with other parties to ensure that consent is obtained in accordance with the requirements of the HT Act 2004 and the HTA's Codes of Practice
- 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.
- Language translations are available when appropriate.

  Information is available in formats appropriate to the situation.

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

- There is suitable training and support of staff involved in seeking consent which addresses the requirements of the HT Act and the HTAs Codes of Practice
- Records demonstrate up-to-date staff training
- Competency is assessed and maintained