University Hospitals Plymouth NHS Trust

STANDARD OPERATING PROCEDURE

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION

The definitive versions of all UHPNT RD&I Dept SOPs appear online, not in printed form, to ensure that up to date versions are used. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the Trust's website: https://www.plymouthhospitals.nhs.uk/research-sops

The Use of Human Tissue in Research

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Date: 21st Jan 2019

1 Purpose and Scope

This SOP has been produced in accordance with the Human Tissue Act 2004 and the Codes of Practice issued by the Human Tissue Authority (HTA). The SOP outlines the current procedures to be followed when Investigators intend to use human material in their research.

The purpose of the Act is to provide a consistent legislative framework for issues relating to whole body donation and the taking, storage and use of human organs and tissue. It makes consent the fundamental principle underpinning the lawful storage and use of human bodies, body parts, organs and tissue and the removal of material from the bodies of deceased persons.

The HTA was established in April 2005 and it is the Authority which regulates the use of human tissue for the Scheduled Purposes covered by the Human Tissue Act, one of which is research. The HTA grants licences to establishments in order that they can carry out certain activities lawfully. One such purpose is the storage of tissue for research. A licence is not required to store tissues for research, as long as it is part of an ethically-approved study, for the duration of the study. The Department of Cellular Pathology holds a licence for long term storage of tissues, which includes storage for research. Information on licensing and a Codes of Practice can be found on the HTA website (http://www.hta.gov.uk/licensingandinspections.cfm)

The regime to be set up under the Human Tissue Act does not vary greatly from the good practice guidelines issued by the Department of Health and Medical Research Council. Investigators using human tissue in their research must adhere to the Codes of Practice adopting the following procedures when using human tissue in research. The code of practice for research can be located at: https://www.hta.gov.uk/sites/default/files/Code%20E%20-%20Research%20Final_0.pdf.

In scope: research hosted by, and/or sponsored by UHPNT that collects human tissue material/samples.

Definitions

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
DI	Designated Individual – The person who is authorised and who supervises activities under a licence issued by the HTA.
GCP	Good Clinical Practice

HRA	Health Research Authority
HTA	Human Tissue Authority
MHRA	Medicines and Healthcare products Regulatory Agency
MTA	Material Transfer Agreement – a contract that governs the transfer of tangible research materials between two organisations, when the recipient intends to use it for his or her own research purposes.
UHPNT	University Hospitals Plymouth NHS Trust
RD&I	Research, Development & Innovation
REC	Research Ethics Committee
RO	Research Office
SOP	Standard Operating Procedure
TCC	Tissue Collection Centre

2 Who should read this document?

Staff involved in setting up and conducting research involving human tissue, Chief Investigators (CI), Principal Investigators, Trial Managers/Co-ordinators, Laboratory personnel, Research Nurses & Midwives, RD&I Managers and RD&I Clinical Trial Administrative staff

3 Procedure to Follow

Within the Human Tissue Act, human tissue is referred to as ***'relevant material'*** and this is defined as ***'material that has come from a human body and consists of, or includes, human cells'***. Under the Act, "relevant material" means material, other than gametes, which consists of or includes human cells.

References to relevant material in the Act *do not* include:

(a) embryos outside the human body, or

(b) hair and nail from the body of a living person.

The Human Tissue Authority has furthered defined 'relevant material' and has divided tissues into three categories as follows:

3.1 Categories of relevant material

3.1.1. Specifically identified relevant material

This includes material like bodily organs and tissues, consisting largely or entirely of cells, and clearly identifiable and regarded as such. This category of relevant material includes human bodies, internal organs and tissues, skin and bone; and specifically the following:

- stem cells created inside the human body
- embryonic stem cells
- non blood derived stem cells
- umbilical cord blood stem cell
- bone marrow
- primary human cell cultures

BUT NOT

- cultured cells which have divided outside the human body
- artificially created embryonic stem cells
- cell lines
- extracted DNA
- plasma extracted DNA

3.1.2. Processed material

If it is generally agreed -as a result of the process – to leave a processed material either cellular or acellular, then the presumption should be that all the processed material should be regarded as such. The HTA would rely on the stakeholders's 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 to be regarded generically as relevant material; while plasma or serum, for example, will be regarded as not. The two latter processed materials, widely produced from blood taken for treatment, are however examples of where 'normal expectations' may well need to be exercised.

3.1.3. Bodily waste products (including excretions and secretions)

Bodily waste is a less well characterised group of material. Nevertheless the Authority considers it important to provide a framework of guidance. The Authority considers bodily waste should normally be regarded as relevant material: the Act cannot be denied on this point. The Act's wording is clear and reflects the possibility that even a single cell can be subject to research. While acknowledging the views of stakeholders who have argued for greater individual discretion, it would be inappropriate to encourage people to grant themselves an exemption on the basis of their own interpretation of the Act. However the Authority may be able to offer nuanced advice in specific instances. There will be cases where a stakeholder believes that material, intended for a scheduled

purpose, is actually acellular. In such cases the stakeholder would need to consult the Authority, and we would then refer the case for advice to a members' panel if necessary.

3.2. Procedure to be followed by Investigators prior to, during and after a research project has ended

3.2.1. Prior to Research Project Commencing

Under the Research Governance Framework, there is no requirement for HRA permission for research for the establishment of research tissue banks in the NHS. Applications to the HRA through IRAS are not required as all NHS organisations are expected to have included management review in the process of establishing the tissue bank and, where applicable, applying for licensing of a tissue bank.

Research permission is also not required by collaborators at Tissue Collection Centres (TCCs) who provide tissue samples, other biological material and/or data under the terms of a supply agreement between the care organisation and the tissue bank. TCCs are not research sites for the purposes of the Research Governance Framework.

The Trust RD&I Office is responsible for the review and oversight of proposed and current Research Tissue Banks held within the Trust and if the Trust is acting as a Tissue Collection Centre are notified to the RD&I Dept. to ensure compliance with the Human Tissue Act.

Under the Human Tissue Act 2004, storage of 'relevant material' (material from a human body consisting of or including cells) for scheduled purposes in England, Wales or Northern Ireland requires a licence from the HTA.

The scheduled purposes include research in connection with disorders or the functioning of the human body.

A licence is not required for storage in connection with a specific research project with approval from a REC. This exemption does not apply to tissue banks storing relevant material for use in future research.

Where voluntary application is made to a REC for ethical review of a research tissue bank, a copy of the licence will be required by the REC as a condition of a favourable opinion.

Applications to the HTA for licensing are made by submitting the appropriate compliance report. This is outside the scope of IRAS.

1. Investigators will notify the Research Governance Manager of their intention to use human tissue samples in their project at the time of registration of their study with the RD&I Department.
2. Investigators will refer to the HTA website for advice on the use of tissue in research and will familiarise themselves with the content of the Human Tissue Act and the Codes of Practice issued by the Human Tissue Authority.

3. Investigators will ensure that protocols cover the following:
   a) the source of tissue samples to be used in research
   b) the consent procedures for use of donated tissue samples in research
   c) the anonymisation arrangements for tissue samples if they are to be anonymised
   d) the storage arrangements for all tissue samples
   e) the arrangements for the recording of the collection and use of tissue samples
4. The Investigator must ensure that the project has the appropriate Research Ethics Committee (REC) approval and has been authorised by the Health Research Authority (HRA) prior to commencing the research.

3.2.2. During the conduct of the Research Project

1. Investigators intending to use **non-surplus tissue** samples in research must always obtain informed consent from the donor for this use. The signed informed consent forms must be kept in both the investigator site file and in the medical notes of the patient.

   It is no longer necessary to obtain consent for the use of **surplus** tissue samples obtained from **living donors** in research providing the research has been ethically approved by a recognised REC and the samples will be ***anonymised*** **(see section 3 exemptions from consent provisions of the Human Tissue Act).**

   Under the Codes of Practice issued by the HTA, anonymised samples need not be 'permanently and irrevocably unlinked'. Although the researcher using the material **must not** hold any information that identifies a donor, links can be retained to the donor of the tissue sample by an intermediary person or organisation acting to protect the identity of the donor.

   The HTA Codes of Practice also state that, in certain circumstances, Ethics Committees can stipulate irrevocable unlinking and may also stipulate that consent *is* required.

2. Where investigators are required to obtain a donor's consent, consent for the use of non-surplus tissue should be recorded in writing within the participant information sheet/consent form. Investigators must ensure that Patient Information Sheets state clearly the intention to use in research tissue samples taken at clinic or surgery. There must be a section on the Consent Form which allows for the recording of a donor's explicit consent for the use of their *tissue.*
3. Where an investigator cannot obtain consent from a donor due to the disability/incapacity of that individual, the consent process must be witnessed by another party independent of the research team. The Human Tissue Act details those individuals with 'qualifying relationships' allowing those individuals to give consent on behalf of the incapacitated donor.

Qualifying relationships are to be ranked in the following order:

a. spouse or partner
b. parent or child
c. brother or sister
d. grandparent or grandchild
e. child of a person falling within (3)
f. stepfather or stepmother
g. half-brother or half-sister
h. friend of longstanding

Where is it not possible to obtain consent for the use of tissue from an adult lacking the capacity to consent, the use of tissue from such individuals may be used without their consent if:

a. it is in the best interests of the incapacitated person
b. it will allow for clinical research involving tissue from incapacitated persons in line with the Clinical Trials Regulations (Medicines for Human Use (Clinical Trials) Regulations 2004 and Medicines of Human Use (Clinical Trials) Amendment Regulations 2006)
c. to allow for storage and use of tissue from incapacitated persons consistent with the provisions of the Mental Capacity Act.

4. Tissue samples from the deceased must only be used in research when appropriate consent has been obtained from an individual who had a 'qualifying relationship' with the deceased or if the individual give his/her consent whilst living and with capacity to consent.
5. Investigators must ensure all tissue samples taken and kept in storage for the purposes of a research project are appropriately labelled upon collection of the sample.
6. Investigators must keep a record of the tissue samples they receive during the conduct of a research project in order that the origin, storage location, use and final destination of tissue samples collected as part of the research can be traced. A copy of a tissue sample collection record and tissue sample tracking form must be kept by the investigator. See Appendix 1 and Appendix 2 of this SOP for an example of a tissue collection record and tissue sample tracking form. Traceability of tissue samples is a requirement of the Human Tissue Authority Codes of Practice.

3.2.3. Following the end of the Research Project

1. The Investigator must inform the Research Ethics Committee and the RD&I Department of the end of the study.

2. The Investigator must ensure that any tissue samples remaining following the end of the study are either destroyed or transferred to a licensed tissue bank in accordance with the ethically-approved protocol. Contact the RD&I Department for details of licensed tissue banks.

   Disposal should be handled sensitively. Please seek advice on appropriate disposal methods; applicable policies in your area were available should be followed. The HTA Code of practice 5 'The Removal, Storage and disposal of Human Organs and Tissue' may be accessed from HTA's website and can be followed as guidance.

3. Investigators who wish to retain tissue samples remaining following the closure of a research project must ensure that the samples are stored in a HTA licenced tissue bank within the Trust.

3.3. DNA Analysis and Research

According to the HTA Codes of Practice on Consent:

The consent requirements of the Act do not make separate provision for DNA or other genetic analysis. Where consent has been given for the removal, storage or use of tissue and organs for Scheduled Purposes, it is lawful to carry out that activity by means of DNA analysis. This does not mean that it would always be good practice to do so without seeking specific agreement to the genetic analysis.

While consent makes it lawful to store and use tissue for Scheduled Purposes, it is an offence under section 45 of the Act to have any bodily material (i.e. material which has come from a human body and which consists of or includes human cells) with intent to analyse the DNA in it without qualifying consent, subject to certain exceptions. Unlike the other parts of the Act, which do not apply to Scotland, this offence applies to the whole of the UK.

One such exemption to the offence provision is:

Research in connection with disorders or functioning of the human body, provided the bodily material comes from a living person, the person carrying out the analysis is not in, and not likely to come into, possession of identifying information and the research is ethically approved by a research ethics authority. The Secretary of State may also specify the circumstances in which the High Court, or in the case of Scotland, the Court of Session may order that use of the results of DNA analysis for research purposes is an 'excepted' purpose.

3.4. Research Ethics Committee Approval of Research Involving Human Tissue

The HRA has made a series of changes to facilitate ethical review of research involving human tissue. These include:

1. A REC approval process for licensed tissue banks, allowing tissue to be released to research projects without further REC approval within the conditions agreed in the original ethical approval.
2. Where this “generic ethical approval” applies, storage of the tissue by the end user researcher will not need an HTA licence. Once the research project is finished the researcher will need to transfer the tissue to a licensed tissue bank, seek their own licence or, as a last resort, dispose of the material.
3. The establishment of 'flagged' RECs which will specialise in tissue bank applications. Applications to undertake specific research projects involving tissue may continue to be submitted to any HRA REC.

To apply for ethical review either for a specific project or a tissue bank, you will need to select the relevant option on the Integrated Research Application System (IRAS) to generate the appropriate version of the REC application form. Question-specific guidance is available for applicants on-line. Further guidance is available in the SOPs for Research Ethics Committees, see Section 12: Research involving human tissue (http://www.hra.nhs.uk/documents/2017/01/standard-operating-procedures-version-7-2.pdf), http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/human-tissue-2/ and https://www.hta.gov.uk/policies/information-research-tissue-banks .

IRAS options:

1. *Study limited to working with human tissue samples*

Research in this category is based entirely on the use of human tissue samples or other human biological material. It must involve no change to the normal clinical care or treatment of participants. There will be no participant contact or observation other than to collect samples and seek informed consent, where appropriate.

This category applies to specific research projects using samples. Where a favourable ethical opinion is given, this will apply for the duration of this project only. To apply for ethical review of a licensed research tissue bank or a research database, the appropriate category should be selected.

If this option in IRAS is selected, supplementary questions will appear about the proposed use of the human tissue samples in your study. The version of the form applicable to your project will depend on the answers given to these questions. All options that apply should be ticked.

2. *Research using surplus or existing samples identifiable to the researcher*

This option applies for research using residual tissue left over from routine clinical or diagnostic procedures, or existing stored samples from an archived collection or tissue bank, where the samples will be identifiable to the researcher.

3. *Research tissue bank*

Organisations responsible for the management of research tissue banks (RTB) anywhere in the UK may apply for ethical review of their arrangements for collection, storage, use and distribution of tissue. A "research tissue bank" (or "biobank") is defined as:
A collection of human tissue or other biological material, which is stored for potential research use beyond the life of a specific project with ethical approval or for which ethical approval is pending.

Applications are not restricted to collections of human tissue within the definition of "relevant material" under the Human Tissue Act 2004.

If your research is a specific research project involving human tissue you should select another option on the Project Filter in IRAS.

Licensing requirements

Under the Human Tissue Act, tissue banks in England, Wales and Northern Ireland storing relevant material for use in as yet unspecified research must obtain a licence from the Human Tissue Authority (HTA).

When applying for ethical review of RTBs, applicants will be expected to provide the REC with a copy of the licence as a condition of ethical approval except where:

the RTB is established in Scotland;

the biological material to be stored for use in research is outside the definition of "relevant material" under the Human Tissue Act, e.g. DNA, plasma, serum, cell lines.

Detailed guidance on licensing is available from the HTA.

3.5. Import and Export of Tissue

The HTA has a Code of Practice for 'Export of Human Bodies, Body Parts and Tissue. This Code of Practice is available on the HTA website.

Investigators who wish to involve UHPNT in the import or export of human tissue must ensure that such activity is only carried out under the terms of a Material Transfer Agreement.

Please contact the RD&I Department for further information and advice regarding the import and export of tissue and indeed for all issues relating to the use of human tissue in research.

3.6. Guidance: Exemptions from the Licensing & Consent Provisions of the Human Tissue Act

The HTA has published the following guidance covering the exemptions to the licensing provision of the Human Tissue Act with relation to research.

3.6.1. Exemption from the Licensing Provisions of the Human Tissue Act

Licensing Exemptions – Tissue from the Deceased

Storage of relevant material which has come from the body of a deceased person, is exempted 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 REC. The REC giving the approval must be a committee recognised under the Medicines for Human Use (Clinical Trials) Regulations 2004 or a committee which is established and recognised under existing systems for ethical review of health research in England, Wales or Northern Ireland. The committee will normally be a HRA Research Ethics Committee.

Licensing Exemption - Tissue form the Living or the Deceased

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 rather than a week or longer.

Storage of relevant material is exempt from licensing where the person storing it is intending to use the material for transplantation:

- and the material is an organ or part of an organ (if it is to be used for the same purpose as the entire organ in the human body) or
- the storage is for a period of less than 48 hours.

Licensing exemptions – Tissue from the Living

Storage of relevant material which has come from the body of a living person is exempt where the person storing it is intending to use it for:

- Determining the cause of death
- Establishing after a person's death the efficacy of any drug or treatment administered to them
- Obtaining information which may be relevant to another person
- Public display
- Clinical audit
- Education or training related to human health
- Performance assessment
- Public health monitoring
- Quality assurance
- Qualifying research (see definition above).

NOTE: A licence is not required to store DNA.

3.6.2. Exemptions from the Consent Provisions of the Human Tissue Act

Existing Holdings of Tissue for Use in Research

The Human Tissue Authority has issued the following guidance regarding existing holdings of research:

The Human Tissue Act indicates that existing holdings are exempt from the consent provisions of the Human Tissue Act. 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 Act is commenced (1st September 2006) for use for a Scheduled Purpose. This exemption does not apply to the storage or use of dead bodies held for anatomical examination, which are dealt with separately under Section 10 of the Human Tissue Act (see below). This means that existing holdings of, for example, pathological and former anatomical specimens can continue to be stored and used for education and training related to human health without the need for appropriate consent under the Human Tissue Act.

Section 10 deals with existing anatomical specimens, which are different from former anatomical specimens, and essentially comprise bodies or body parts donated for dissection under the Anatomy Act 1984 (AA 1984) (in the 3 years pre commencement of Human Tissue Act) but where the anatomical examination has not been completed by 1 September 2006. The effect of section 10 is that there is deemed to be appropriate consent under the Human Tissue Act for the storage and use of these dead bodies for anatomical examination where an authority exists under the Anatomy Act 1984. Likewise, where the authority under the Anatomy Act 1984 extended to possession of parts of the body, appropriate consent will be deemed to exist for the storage and use of such parts for research, and education and training.

Consent and Anonymisation of Tissue Samples

The Human Tissue Authority has published the following guidance on its website:

An exemption in the Human Tissue Act 2004 (Human Tissue Act) allows tissue and cells to be stored without a licence for a research project that has appropriate ethics approval. 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. The HTA encourages the taking of informed and generic consent at the outset, as the default position. This allows tissue to be used for different research projects over an unspecified period of time. It is preferable to developing complex systems for keeping the samples unlinked and mitigates the need to obtain repeat consent for each research project. More information is available in the HTA's Code of Practice on Consent.

3.7. Adverse event and reaction reporting

Under the European Union Tissue and Cells Directive (EUTCD), the HTA is required to set up a system for tissue establishments to report serious adverse events and reactions. The definitions of serious adverse events and reactions as set out in the EUTCD are as follows:

Serious Adverse Event (SAE)

'serious adverse event' means any untoward occurrence associated with the procurement, testing, processing, storage and distribution of tissues and cells that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which might result in, or prolong, hospitalisation or morbidity.

Serious Adverse Reaction (SAR)

'serious adverse reaction' means an unintended response, including a communicable disease, in the donor or in the recipient associated with the procurement or human application of tissues and cells that is fatal, life threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity.

Online HTA notification system

Only Designated Individuals (DI) at licensed establishments will currently have a user name and password. Therefore, anyone wishing to use this system who is not reporting from a licensed establishment will be unable to at present.

A requirement of the EUTCD is that you submit notification of a serious adverse event/reaction which is then followed up by the submission of a report once local investigations have taken place. As a the DI as a user will have a 'workspace' containing a searchable library of all UHPNT notifications and follow up reports which only the DI can access.

Please note that this system does not replace existing local reporting arrangements (see 3.7.1.). In addition to local arrangements you are now required to report to the HTA what you as a professional consider to be a serious adverse event / reaction (not relating to whole organs), as guided by the definitions above. If you are unsure whether to report, please contact a member of the SAEARs team on 020 7269 1900 or email saears@hta.gov.uk

3.7.1. Local Reporting Procedure

The aim of the procedure is to ensure that incidents are reported promptly and feed into the Trust's DATIX incident reporting system.

All adverse incidents and events relating to the use of human tissue for research should be reported to the person designated at the relevant site as listed in Table 1.

If you cannot contact these people then report the incident to the Trust Research Governance Manager (details also listed in Table 1).

Table 1. Contact details for the Persons Designated

Dr David Hilton	Consultant Pathologist HTA - Designated Individual (DI)	Tel Ext: 31360 davidhilton@nhs.net
Dr Patrick Medd	Consultant Haematologist HTA - Designated Individual (DI)	Tel Ext: 52393 patrick.medd@nhs.net
Dr Chris Rollinson	Research Governance Manager	Tel Ext: 31045 crollinson@.nhs.net

Handling and Investigating Incidents

HTA definition of an adverse event is
Any event that:

- caused harm or had the potential to cause harm to patients, staff or visitors;
- led to or had the potential to lead to a breach of security of the premises and the contents contained therein;
- caused harm or had the potential to cause damage to stored human tissue (including loss);
- gave rise to an internal inquiry.
- resulted in a breach of the Human Tissue Act or the Codes of Practice

The primary areas, related to research and the use of human tissue where adverse incidents (or near misses) should be reported and investigated are listed in table 2 below.

It is the responsibility of any member of staff involved in, discovering or observing an adverse incident (involving human tissue in research) to report it as soon as possible to the DI. This should be during the same working day, but certainly within 24 hours. You should give as much detail as possible about the incident.

All human tissue related incidents that are reported will be reviewed at the DI and where required reported onwards. Where the incident is considered to be serious the Trust Risk office will be notified. All incidents reported through the Trust DATIX incident reporting system will be handled and investigated according to the Trust Policy for adverse Incident Reporting. Where the incident is identified as being human tissue and research related the Risk office will ensure the Research Governance Manager is informed.

Where appropriate the Person Designated will investigate the incident. By taking into account the points set out in Table 3 the investigation should highlight where there are areas of poor performance/practice, systems failure, and violation of procedures or the need for a change of practice.

The identification of underlying key causes will provide a means to identify isolated weaknesses in systems, patterns of behaviour through which events may develop into incidents and practices that may have become unsafe.

The standards set out by the HTA require that all adverse incidents or near misses involving the removal, use, storage and disposal of human tissue for research purposes should be reported and investigated to ensure lessons are learnt and action taken to minimize the risk of recurrence.

Table 2. Incident Reporting Trigger List

Type of incident
Consent
- Human tissue removed from a patient without appropriate consent - Human tissue stored without appropriate consent - Human tissue used without appropriate consent - Consent for research not filed in patients notes but a record is present in the study file - Human tissue used for a research study that has not been approved by a NHS REC - Staff member seeking consent is not appropriately trained
Governance and quality
- Wrong version of SOP in use/ failure of change control mechanism - Breach of Data protection/ confidentiality. - Research material sent off site without appropriate review/ authorisation/ material transfer agreement
Specimen acquisition/ research request forms
- Wrong type of specimen - Incorrectly labelled specimen - Specimen in wrong format - Specimen from wrong patient
Tracking
- Labelling error - Stored research material not on Item Tracker - Discrepancy between Item Tracker and storage location - Incomplete audit trail resulting in failure to trace a specimen
Storage
- Cold storage breakdown with alarm failure. discovered in time – near miss - Cold storage failure – monitoring and backup failure → disposal of material - Unauthorised access to storage facilities/ breach of security - Human Tissue Stored in an inappropriate facility.
Disposal
- Human tissue disposed of with general clinical waste - Incorrect or failure to label Human tissue waste - Reason for disposal of stored research material not documented
Transportation
- Material lost during transportation - Material quality compromised during transport

Table 3 Investigation - Points to consider

SOP	Is there an SOP to cover the procedure?	Yes/No
	If yes	
	Is it adequate?	
	Does it need to be revised?	
	Did the individual know about and follow the SOP?	
Training	Was the individual appropriately trained?	Yes / No
	If not, why not?	
	No training available	
	Training available but not advertised appropriately	
	Training available and advertised but individual did not attend	
	Other (explain)	
Equipment / facilities	Was the equipment/facilities/ security fit for purpose?	Yes / No
	If not, why not?	
Previous occurrence	Have similar incidents happened before?	Yes / No
	If yes, give details	

4 Document Ratification Process

The review period for this document is set as ***default of three*** years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by the ***RD&I Manager or their Deputy***.

Non-significant amendments to this document may be made, under delegated authority from ***a Senior RD&I manager***, by the nominated author. These must be ratified by ***a Senior RD&I manager***.

Significant reviews and revisions to this document will include a consultation with ***appropriately knowledgeable staff***. For non-significant amendments, informal consultation will be restricted to ***staff*** who are directly affected by the proposed changes.

Dissemination and implementation

4.1. Dissemination of this SOP

4.1.1. New SOPs and new versions of existing SOPs: The Research Governance Manager will be responsible for ensuring authorised SOPs are uploaded on the RD&I intranet site. Internal Trust Staff are expected to use the RD&I intranet site to access latest versions of SOPs and to check the website regularly for updates.

Notice of new or amended procedural documents that have undergone a major amendment will be given *via* the following routes:

- Inclusion in the Trust weekly e-bulletin Vital Signs
- Direct email to Trust Researchers and or teams

4.2. Training in this SOP

4.2.1. All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP.

5 Reference material

Human Tissue Authority (HTA).

Website: http://www.hta.gov.uk/

https://www.hta.gov.uk/policies/information-research-tissue-banks

Health Research Authority (HRA)

HRA REC SOPs - Section 12: Research involving human tissue:

http://www.hra.nhs.uk/documents/2017/01/standard-operating-procedures-version-7-2.pdf

http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/human-tissue-2/

Appendices:

Appendix 1 Tissue sample collection form

Appendix 2 Tissue sample tracking form

Appendix 3 Flow diagram of the licensing for storage of human tissue for research

Appendix 4 Flow diagram of the consent for the retention and use of human tissue.

Appendix 1 Tissue Sample Collection Form

Study No:	
Study Title	
Investigator name:	

Subject No	Subject consent (dd-mmm-yyyy)	Date sample collected (dd-mmm-yyyy)	Sample type	Storage location & type of facility[1]	Storage period		Final location[2]	Person Responsible
					Form	To		

[1] Please specify full address and type of storage facility

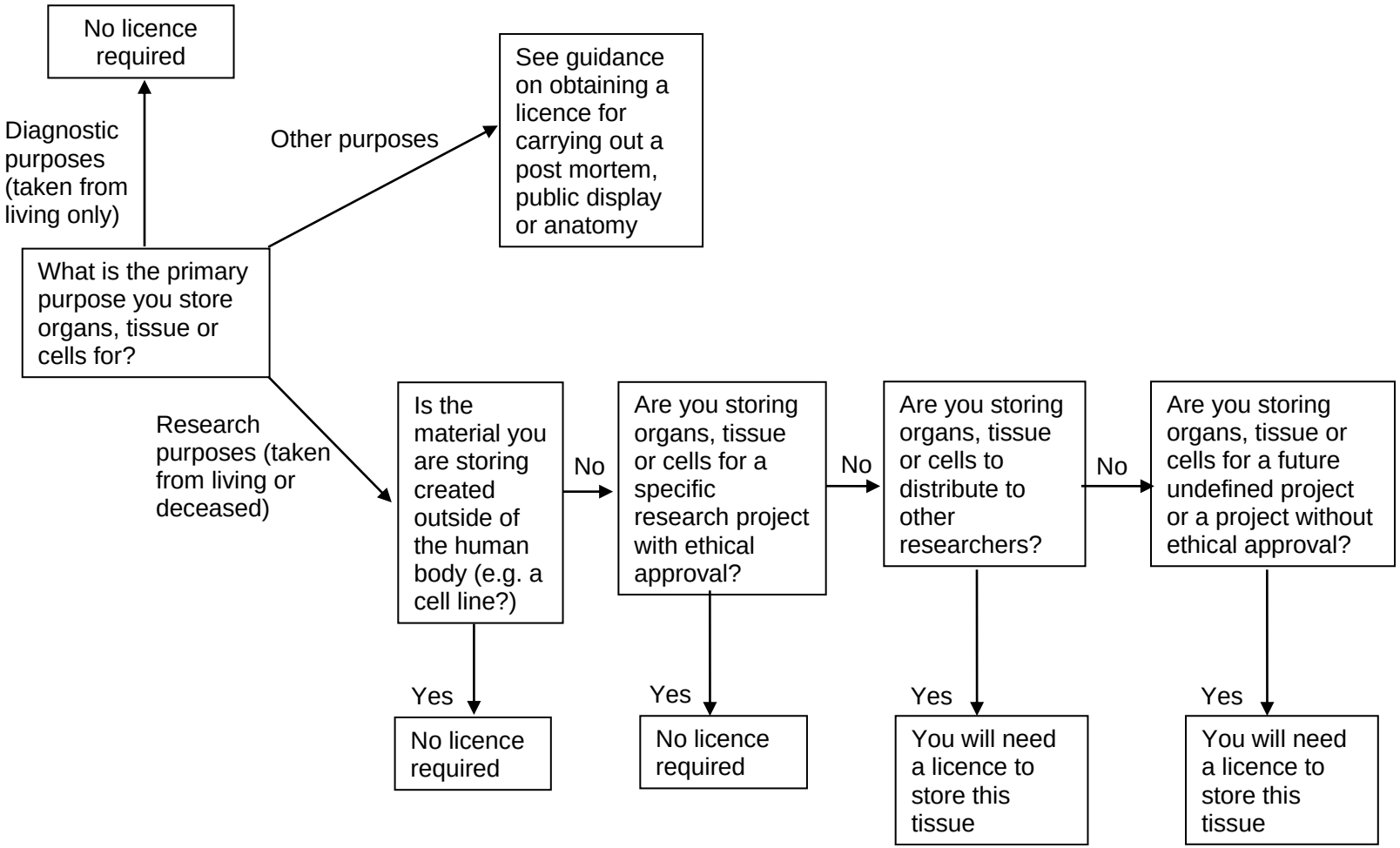
[2] Please specify name of recipient of tissue (e.g. academic collaborator or Commercial company) and location

Appendix 2 Tissue Sample Tracking Form

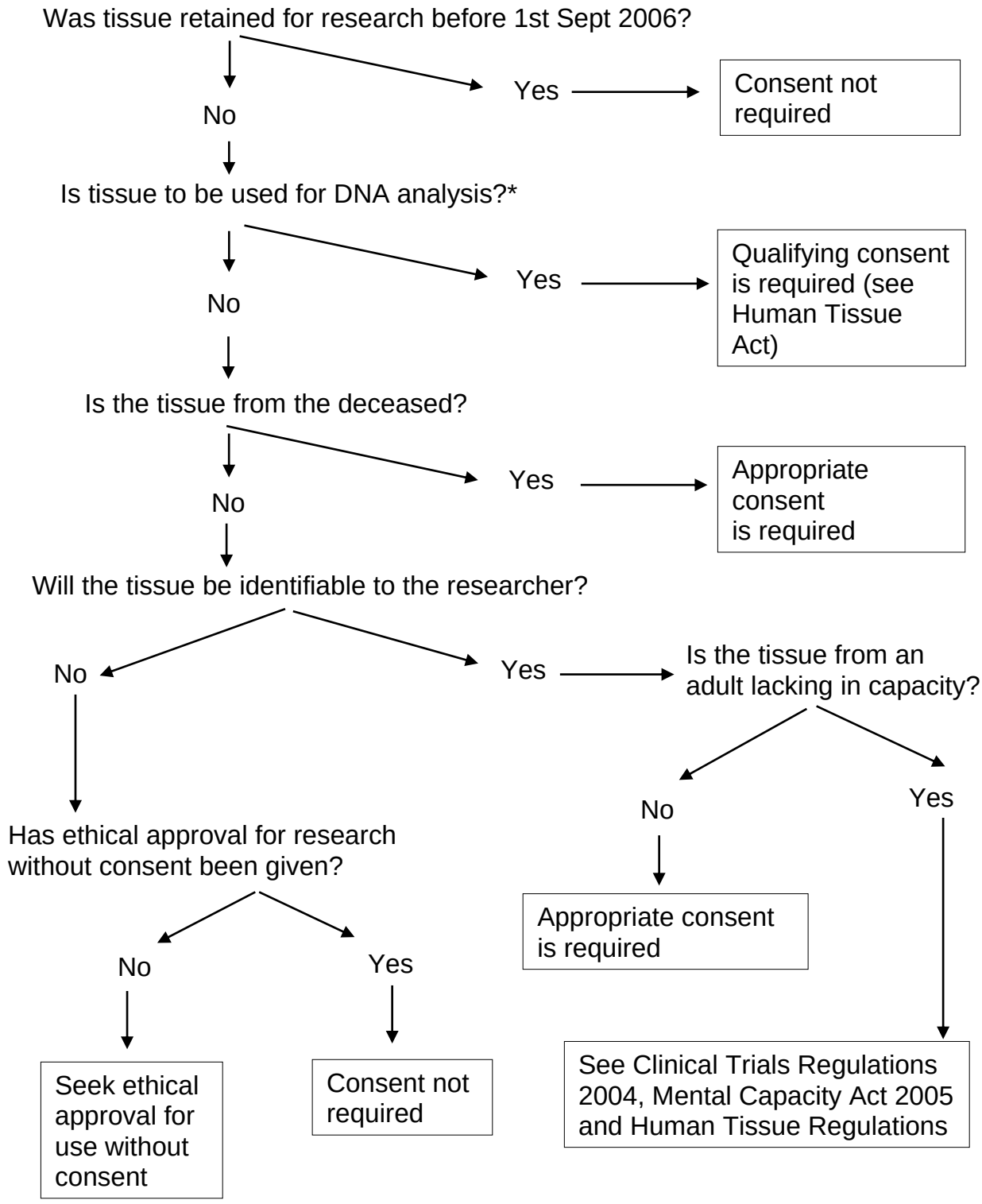
Study No:	
Study Title	
Investigator name:	

Sample No	Date Sample Taken from storage for Analysis (dd-mmm-yyyy)	Sample storage location during analysis	Outcome of analysis	Sample returned to original storage location (freezer/fridge/ archive?	Final location of sample	Person Responsible	Additional Information

Appendix 3. Licensing for storage of human tissue for research



Appendix 4. Consent for the retention and use of human tissue.



* This question applies UK-wide and includes nail, hair and gametes

6 Amendment History

Version Number:	2.1
Date Of Amendment:	Aug 2017
Details Of Amendment:	Updated logo and Trust name.

Version Number:	2.0
Date Of Amendment:	Aug 2017
Details Of Amendment:	Updated SOP template and numbering system. Reviewed and updated SOP.

Version Number:	1.1
Date Of Amendment:	Mar 2012
Details Of Amendment:	Cover page - Change of SOP location address