Guide to Completion of the Research Licence Application

The following activities can only take place under the authority of a licence from the Human Tissue Authority:

- The storage of a body of a deceased person, or relevant material[1] which has come from a human body, for use for a Scheduled Purpose[2].

This document outlines the legal framework of the licensing system, explains the application process and provides guidance on how to complete the application form.

Our Code of Practice E and the Research licensing standards and guidance provide additional guidance on the licensing requirements for the Research sector.

The storage of human tissue for research, and its removal from the deceased, is licensed by the HTA. The HTA does not license the 'use' of tissue for research and it does not have a role in approving individual research projects.

General

1. The Human Tissue Authority (HTA) was established under the Human Tissue Act 2004 (HT Act). The HTA licenses a number of activities and undertakes inspections of establishments carrying out these activities to ensure the requirements of the HT Act are being met.
2. We operate a continuous licensing system, with an annual licensing fee, although in some circumstances we can issue fixed-term licences.
3. The HTA must receive an application before it can grant a licence. The application must specify the premises at which the licensable activities will take place. Where the establishment has multiple sites, such as a main site with remote satellite sites where bodies, body parts or tissue samples are stored, we can accept a single application, provided:
    - the same Designated Individual (DI) is appointed for all sites; and
    - all sites work to the same procedures and governance arrangements.
4. We issue separate licences for the hub and for each satellite site, under the same licensing number. Satellite sites are eligible for a reduced licence fee.

[1] Go to https://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004 for more information on relevant material

[2] See Schedule 1 of the HT Act (Scheduled Purposes) Part 1 and Part 2

Completing and submitting a licence application

5. Licence applications must be downloaded from the HTA website and submitted by email to licensing@hta.gov.uk.
6. The application form has four sections:
    - Information about the establishment
    - Information about the DI and the Licence Holder
    - Information about how the HTA licensing standards are met
    - List of documents to be submitted as part of the application
7. The licensing standards section contains four sets of standards that applicants must assess and evaluate their performance against. These are:
    - Consent
    - Governance and Quality Systems
    - Traceability
    - Premises, Facilities and Equipment
8. The HTA will assess the information provided in the application form and the mandatory documents that must be submitted before the application can be assessed, taking this as evidence on which to base an informed and proportionate licensing decision.
9. Where we have considered it to be helpful, we have included guidance under individual standards to help you assess whether you meet them. You should include details of what procedures you have in place to meet each standard, or if the standard is not being fully met, what you are doing in order to achieve the standard. Key strengths or areas identified for improvement can also be given. For each applicable standard, the establishment should consider the evidence it has to demonstrate whether the standard is not met or met.
10. Where a standard is not applicable please select 'N/A' and provide an explanation of why the standard is not applicable to your establishment.
11. We may contact applicants and undertake a site visit to obtain any additional information or evidence required. This could be at any stage in the application process.
12. Any incorrect or misleading information provided in an application could lead to the revocation of any licence granted.
13. Applicants will need to complete their application and submit all relevant information before the application can be assessed. If an application is not completed due to delays at the establishment within three months from the start of assessment, the applicant(s) will need to repay the licence application fee before their application is further assessed.

14. If an application is rejected following assessment, the applicant(s) will need to repay the licence application fee if they wish to submit a new application.

Granting a licence

15. A licence will be granted when we receive written acknowledgement of the licence offer from the proposed DI and the Licence Holder.
16. If a licence application is refused or granted with conditions and the applicant chooses to challenge this decision, the proposed Licence Holder and/or the proposed DI must give notice of their intention to make representations within 28 days from the date that notice of the proposed licensing decision was given by the HTA (i.e. the date on the Licence Offer/Notice of Proposal letter). This is a strict time limit laid down by statute.
17. Notification of the intention to make representations may be given to the HTA either orally or in writing by the person entitled to make representations. If the request is given orally, it must be made to the Authority's Director of Regulation, one of the Regulation Managers or one of the Heads of Regulation only. The person receiving the oral request to make representations will record the request and confirm this in writing to the person proposing to make representations.
18. The person entitled to make representations must after any oral request then confirm their intention to make representations in writing to the HTA. This may be by letter or email to the Director of Regulation.
19. The following section gives specific help on completing the Application Form. Please contact us by emailing licensing@hta.gov.uk if you need further information about any part of the application form or our process for considering licence applications.

How to complete the application form

Establishment Information

20. Establishment name

    Please provide the name of the organisation on whose premises the activities will take place. Careful consideration should be given to where the licensed activities are going to take place and whether they extend to more than one area within the premises. Include the department name if applicable.

21. Establishment address

    A licence application must specify the premises where the activities are to take place. The address of the main site should be stated in this section. Where the licensed activity will

take place at more than one premises, such as a main site with satellite sites, a separate satellite licence would be needed for each site, however a single application for multiple licences may be made. Details of satellite sites should be recorded in the relevant section.

22. Names of person(s) who have consented to be designated on the licence (where the establishment is applying for a licence(s) on single premises)

    The HT Act allows the DI to designate persons on the licence, with their agreement. Persons Designated can support a DI in overseeing licensable activities.

Satellite Sites

23. Address of satellite site premises and activities to be licensed

    Satellite sites are premises under the same governance arrangements as the main site (hub) and are supervised by the same DI. Each satellite site will have its own licence.

24. Names of person(s) who have consented to be designated on the licence at the satellite premises.

    There should be a primary Person Designated at each satellite site who can direct licensable activities at the site and is accountable to the DI. Please provide the name of the primary Person(s) Designated on the licence for the satellite premises and any additional persons to be designated on the licence of the satellite premises.

Application to be Designated Individual (DI)

25. Information about the role of the DI is available on our website.

26. With regard to the organisational structure of the establishment, please indicate the lines of responsibility between the DI and any persons engaged in licensed activities.

    We must be satisfied the DI is able and willing to supervise the licensed activities. The relationship between the DI and those working under the licence should be described here, as well as the DI's position in the overall governance structure.

27. Please explain how the DI ensures that staff, who will be working under the licence, are appropriately qualified and trained in techniques relevant to their work and continuously update their skills.

    The DI must ensure that suitable practices are carried out by those undertaking the licensed activities; staff training is an important part of this. The DI's role in ensuring that staff working under a licence are suitably qualified and trained should be described here.

28. Declaration
    The DI must read and acknowledge each statement in this section.

Application to be Licence Holder/Corporate Licence Holder

29. The applicant can be a person or a corporate body and must be suitable to hold the position of Licence Holder. If the applicant is a corporate body, the application to be a Corporate Licence Holder must be completed by a person suitable to act as Licence Holder contact. The HTA would prefer that this is a different person to the one carrying out the role of the DI.

30. Declaration

    The Licence Holder or Corporate Licence Holder contact must read and acknowledge each statement in this section.

Licensing Standards

31. The licensing standards are separated into four main themes: consent; governance and quality systems; traceability and premises, facilities and equipment. Each of these four sections must be completed.

32. It is important for establishments to demonstrate how they meet HTA quality standards.

List of mandatory documents to be submitted with application form

33. You will need to submit all documents in the following checklist, together with the completed application form, before your application can be assessed.

34. Please note that these do not need to be separate documents, they may be embedded within other governance documents (e.g. the Quality Manual). If that is the case, please provide the relevant document and indicate the page numbers or section where the mandatory document can be found in the relevant ‘Further information on documentation’ section of the application form.

Application Checklist – Mandatory documents	
Consent	
☐	Consent form
☐	Patient information sheet (or equivalent)
Governance and Quality Systems	
☐	Organisational chart
☐	Quality manual
☐	List of SOPs of licensable activities (please note that these must be developed in line with guidance provided for standard GQ1)
☐	Details of induction programme for new staff/training plan for activities related to the licence (for example consent, sample management and storage, traceability, disposal)
☐	A copy of the Adverse incidents policy and SOP
☐	A copy of the SOP covering traceability of relevant material
☐	A copy of all risk assessments relevant to licensable activities (please note that these must be developed in line with the guidance provided in relation to standard GQ6)
Traceability	
☐	All documents that support end-to-end traceability of human material, including disposal
Premises, Facilities and Equipment	
☐	Risk assessment of premises
☐	List of critical facilities, equipment, materials and reagents
☐	Site plan, indicating where storage of relevant material will take place
☐	Information on storage facilities that are/will be available (e.g. number of freezers, fridges, room temperature storage)
☐	Contingency plan for failure in storage area
☐	SOPs for monitoring and testing of storage conditions

HTA Licensing Standards

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 code 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. General guidance Consent is the fundamental principle of the Human Tissue Act 2004 and the HTA Codes of Practice A (Guiding principles and fundamental principles of consent) and E (Research) are the primary sources of guidance for compliance with this standard. For health-related research in general i.e. not limited to that involving human tissue, the HRA provides resources such as template consent forms and participant information sheets.
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.

General guidance

It is important that consent training is not considered a one-off event and that proficiency in seeking consent is upheld. There is no set requirement for the frequency of consent training. Consent-seekers are expected to maintain awareness of current standards through reference to published guidance and relevant policies. Training may need to be updated when legislation has changed, new policies or practices have been implemented,

different research activities are to be undertaken or a significant period of time has elapsed since research activities have been conducted.

Governance and quality system 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.

Guidance

At a minimum, it is expected that most establishments will have standard operating procedures (SOPs) covering the following activities:

- consent;
- collection;
- receipt;
- labelling;
- specimen preparation / preservation;
- storage;
- relevant transport arrangements;
- cleaning and decontamination;
- disposal.

More complex establishments, especially those releasing material, may need to cover more areas in their suite of documents. A standard operating procedure (SOP) should be a clear and accurate representation of an existing procedure or process, preferably set

out in the format of a stepwise guide. SOPs should be understandable to enable new staff to follow a procedure from beginning to end. They should be detailed enough to ensure uniformity between staff in the performance of a specific function and should be followed to the letter by all staff who have been appropriately trained.

People undertaking the processes should be involved in developing the SOPs to ensure that the written procedures reflect actual practices. Regular review of SOPs will help to prevent incremental departure from written processes with passing time and allow establishments to identify improvements.

Establishments should introduce a system to record that staff have read and understood SOPs. If human tissue is to be transferred between establishments, consideration must be given to minimise the likelihood of theft, damage or loss during transport. Some form of formal transfer arrangement, for example, as part of a Material Transfer Agreement (MTA) should define how the human tissue is preserved, any potential contamination risks associated with it; and who is responsible for disposal, if applicable.

We do not specify or endorse any particular format for MTAs; a number of template agreements are publically available and can be dapted to suit individual circumstances. Transportation procedures should also give sufficient detail to ensure the integrity of the tissue.

b) There is a document control system.

Guidance

Governance documents should include:

- Revision history and version number
- ‘Effective from’ date
- Review date (at least every three years)
- Pagination
- Author and reviewer names

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

Guidance

Change control mechanisms should take into account the risks of any planned changes, any validation required, any training required and how implemented changes will be reviewed.

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

Guidance

All staff working under the HTA licence should be aware of the governance arrangements in place, and they should be represented at governance meetings. Overall governance processes should be supported by regular meetings with staff at the establishment who are engaged in licensed activities. Formal meetings should be minuted and the actions should be noted and followed up. Documented minutes of meetings should be distributed to all relevant staff to help to ensure that they are aware of all important information relating to licensed activities at the establishment. National and local information relevant to activities should also be disseminated.

e) There is a system for managing complaints.

General guidance

A formal quality management framework helps to establish minimum expectations for governance and quality systems, and facilitates continuous improvement.

The work of the staff at the establishment must be subject to a system of governance. This means that there should be clear reporting lines and accountability (particularly with regard to individual staff and the DI), documented roles and responsibilities.

Establishments are encouraged to have an over-arching quality document which provides an overview of the establishment's main purpose, organisation and structure and approach to governance and quality. This document should be accessible to all staff involved in licensed activities.

The HTA recommends that establishments adopt a harmonised approach to sample management as there are risks of varying practices where samples being stored for REC-approved projects are managed differently to samples subject to HTA's licensing standards.

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.

General guidance

Audits will demonstrate compliance with our standards and demonstrate whether establishments are meeting the requirements of their own systems.

A documented schedule of audits should be in place at each establishment.

Vertical audits of records and specimens will allow the establishment to

assure itself that specimens and records are fully traceable from consent to disposal.

Records, including records of consent, should be audited regularly to ensure completeness, accuracy and legibility.

Audits should ideally include horizontal audits by staff involved in the processes, to ensure that SOPs accurately reflect actual practices and to identify areas for improvement. All audit findings and related corrective and preventative actions should be recorded to allow the establishment to demonstrate compliance with HTA standards and follow-up outstanding actions.

Audit processes can benefit from being undertaken by a person who is not normally involved in the activity at the establishment: a 'fresh eyes' view. Internal auditors should not be involved in auditing their own work. Some establishments may be able to make use of existing in-house expertise or services.

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.

General guidance

Training and induction packages help to ensure that staff are fully trained on all policies and procedures relevant to their work. Establishments should ensure that training and development plans are in place and that these are reviewed periodically.

Staff should be encouraged to attend professional meetings and training events to ensure that they keep abreast of good practices in their areas of expertise.

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. Guidance Documented records are used by establishments to evidence traceability and ensure a robust audit trail. In this context, traceability refers to the completeness of auditable information about every step in the pathway for the use of relevant material, from consent through to disposal, or the material has been used up entirely. Documented procedures for the creation, review, amendment, retention and destruction of records are required to help to ensure that records are maintained appropriately. SOPs should detail the frequency of document review required to ensure that documents are regularly reviewed and updated as necessary. b) There are provisions for back-up / recovery in the event of loss of records. Guidance Records may be in various formats, including paper based, electronic, or stored on recordable media. A centralised system for the storage of records can help to ensure that records are regularly backed-up. c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing). Guidance Consideration must be given to other relevant legislation, including compliance with the Data Protection Act 1998 where tissue has been taken from the living, and compliance with professional guidelines where applicable.
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. General guidance All establishments licensed by the HTA are required to have an internal system for reporting adverse events and, where necessary, instigating an investigation or root cause analysis.

Clearly assigning responsibilities for incident management is important. As the DI is responsible for licensed activities at the establishment, there should be a process in place to allow them to be made aware of adverse events so that proper investigation and reporting can take place. There should be an adverse incident SOP detailing how adverse incidents are logged, reported, addressed and monitored.

Although there is currently no requirement for establishments in the research sector to report adverse incidents to the HTA, if a DI has concerns about an adverse event, they are encouraged to contact us for further advice.

Relevant examples of adverse events include:

- specimen loss;
- missing or incorrect documentation;
- security breach;
- abnormalities in storage temperature readings;
- inappropriate disposal.

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.

Guidance

All establishments should identify the risks inherent in the key activities, and procedures should be developed in consideration of and to mitigate these potential risks where appropriate. Establishments may tend to focus risk assessments on health and safety issues which, in themselves, are not sufficient to meet our standards. DIs should also assess the risks associated with licensed activities. Documented risk assessments should include an evaluation of the level of the risk and, where appropriate, the mitigating actions identified and the level of residual risk remaining.

Risk assessments should include the risks relating to the premises, practices and procedures connected with licensed activities, including:

- receiving and/or storing specimens without appropriate consent documentation;
- storing or using human tissue after consent withdrawal;
- storage failure or other damage affecting human tissue quality for useful research;

- loss of human tissue;
- sample mix-up or loss of traceability;
- transport of specimens to and from the establishment;
- security arrangements;
- incorrect disposal.

b) Risk assessments are reviewed regularly.

Guidance

Risk assessments should be reviewed periodically (typically, every 1-3 years) and the actions to mitigate risks updated as necessary. Risk assessments should also be reviewed following an incident.

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

Guidance

By documenting risk assessments, staff are made aware of identified risks, which helps to prevent risks materialising and informs the development of procedures and relevant documentation.

Traceability standards

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.

General guidance

Where relevant, through their coding and records systems, HTA-licensed establishments should be able to demonstrate their awareness and ability to track ethical approval expiry dates and any relevant conditional agreements, such as consent opt-outs.

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.

General guidance

Establishments should carefully document disposal. Supporting procedures should detail the requirements for recording the details of disposal, including the date, reason and method. Records of disposal should be kept in order to provide a complete audit trail from donation through to disposal.

Premises, facilities and equipment standards

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.

Guidance

The establishment must be clean, well maintained and subject to a programme of planned preventative maintenance. Suitable environmental controls should be in place to avoid potential contamination.

Establishments should periodically review risk assessments of premises, facilities and equipment. This should ideally include an audit of the premises and equipment in order to identify areas requiring rolling maintenance, refurbishment or upgrade. This will help to ensure that remedial actions are implemented in a timely manner so that the premises, facilities and equipment remain fit for purpose.

b) Arrangements are in place to ensure that the premises are secure and confidentiality is maintained.

Guidance

Security measures include the use of locks, alarm systems and protections against unauthorised access.

Establishments are expected to have policies in place to review and maintain the safety of staff, visitors and other relevant people e.g.students or donors.

c) There are documented cleaning and decontamination procedures.

Guidance

Documented cleaning and decontamination procedures should be supported by schedules.

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.

Guidance

Documented temperature monitoring allows establishments to easily visualise and identify when temperatures are out-of-range. It can also demonstrate temperature trends, to identify when storage conditions may be deteriorating and to alert staff to developing equipment failure. Temperature alarms should be regulary tested and manually challenged periodically to ensure that they are operating as expected.

Signs should be added to freezers to define alarm set points for the temperature ranges so that staff are visually reminded of minimum and maximum temperatures.

Where storage is critical, an appropriate remote temperature monitoring alarm and callout system may be required.

Checks and filling of liquid nitrogen dewars should be documented.

Where material can be stored at ambient/room temperature, this does not mean that storage conditions do not need to be monitored.

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

Guidance

The establishment must have contingency arrangements in place should there be an emergency situation that renders the premises unusable for the storage of human tissue; this may need to be through a formalised arrangement with another HTA-licensed establishment for transfer of material.

General guidance

Areas used for storage of human tissue for use in research must provide an environment that is safe for those working under the licence and preserves the integrity of the tissue.

Refrigerators, freezers and other vessels which contain human tissue should be appropriately labelled so that staff are aware of the necessity to maintain the quality, safety and security of such material and prevent mix-ups with other tissues.

Human tissue must be stored in such a way that it minimises the risk of contamination to those working under the licence. If necessary, the DI should work with health and safety personnel to implement environmental controls and appropriate equipment to reduce the risk of contamination.

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.

Guidance

Equipment must be regularly maintained to ensure that it is suitable for use.

Equipment should be made of material that is easy to clean, impervious, non-rusting, non-decaying and non-staining.

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

Guidance

There should be a system for renewing items that are no longer suitable through wear and tear.

c) Staff are provided with suitable personal protective equipment.

Guidance

Staff must have access to the protective clothing, materials and equipment they need.

Glossary

Adverse event	Any event that: • Caused harm or had the potential to cause harm to 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 harm to stored human tissue (including loss) • Gave rise to an internal inquiry. Once an establishment is licensed, any breach of the HT Act or the codes of practice will be considered to be an adverse event.
Code of practice	The HTA codes of practice provide guidance and lay down expected standards for each of the sectors we regulate. There are nine codes available via the HTA website.
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.
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.
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.
Licence Holder (LH)	The person who holds a licence and is responsible for the payment of any fees charged by the HTA. The LH can be a corporate body. Where the applicant is not the proposed DI, the HTA must be satisfied that the applicant is a suitable person to be the holder of the licence.

Person designated (PD)	A person, or persons, nominated by the DI (in writing to the HTA) who has the ability to 'direct' others in relation to the conduct of activities licensed under the Human Tissue Act 2004. There must be a Person Designated at each satellite site who can direct activities that are licensed there and who is accountable to the DI at the main hub site.
Relevant material	Defined by the HT Act as material other than gametes, which consists of, or includes, human cells. In the HT 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 website.
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	This can be either a) a REC recognised or established by, or on behalf of, the HRA under the Care Act 2014 or any other group of persons which assesses the ethics of research involving individuals and which is recognised for that purpose by, or on behalf of, the Welsh Ministers or the Department of Health in Northern Ireland; or b) 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.

Standard operating procedure (SOP)	A document which provides detailed, written instructions to achieve uniformity of the performance of a specific operation, function or task. An SOP must be written with sufficient detail so that someone with limited experience or knowledge of the procedure can successfully reproduce it without supervision.
Surplus tissue	Includes material which has come from a person's body in the course of his receiving medical treatment, undergoing diagnostic testing, or participating in research; or material that is relevant material that has come from a human body and ceases to be used, or stored for use, for scheduled purposes.
Tissue	Any and all constituent part/s of the human body formed by cells.