**Human Tissue Act 2004**

**University of Bristol Code of Practice**

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# Introduction and aims of Code of Practice

This University Code of Practice (the “Code”) has been developed by the Human Tissue Working Group (the “HTWG”) to ensure that the regulatory framework in respect of the Human Tissue Act 2004 (the “HT Act”) and Human Tissue Authority (HTA) Directions, including the HTA Codes of Practice and Guidance (the “HTA Codes”), (together the “Regulatory Framework”) are successfully implemented into the University’s practices, guidance and policies.

The Code provides a resource for anyone working for, or studying at, the University of Bristol with human organs, tissue and cells (together “Relevant Material”) in an educational or research setting.

It also provides guidance about using DNA from Bodily Material (“Bodily Material”) i.e. material which has come from a human body and consists of or includes human cells. Bodily Material is a broader definition than 'Relevant Material', as it includes hair and nails from the living as well as from the deceased and gametes (human sperm and eggs).

It is important for the University to maintain its HTA licences. If staff or students knowingly breach the Regulatory Framework, or the mandatory provisions of this Code, the University’s research and teaching roles may be jeopardized and the University could suffer reputational damage.

Staff and students are reminded that failure to observe the HT Act or this Code may amount to misconduct or gross misconduct and could result in disciplinary action being taken. Failure to comply with the HT Act can lead to criminal penalties and fines for the individuals concerned, the relevant Designated Individual (DI) responsible for the premises in which the activity takes place, and the University.

All those to whom this Code applies should report any known or suspected breaches of this Code and relevant misconduct. Members of staff and students are encouraged to raise concerns about potential breaches of the Code and/or suspected relevant misconduct in the first instance with either their Line Manager (where applicable), the relevant DI or the Head of Research Governance or alternatively in confidence under the Policy on Public Interest Disclosure. The University has a responsibility to investigate allegations of misconduct. It also has a responsibility to protect staff and students from malicious, mischievous or frivolous allegations.

Further information can be obtained from the ‘[Regulations on Research Misconduct](http://www.bristol.ac.uk/secretary/student-rules-regs/)’

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# Part A: Regulatory framework, Licences and the Designated Individual

# Regulatory framework

* 1. **Human Tissue Act 2004**

The HT Act provides a framework for regulating the storage and use of Relevant Material from the living, and the removal, storage and use of Relevant Material from the deceased for Scheduled Purposes. The HT Act makes consent the fundamental principle underpinning the lawful retention and use of Relevant Material from the living or the deceased for Scheduled Purposes. Under the provision of the HT Act consent must be obtained to remove, store or use bodies or Relevant Material for Scheduled Purposes: [Human Tissue Act 2004](https://www.hta.gov.uk/guidance-professionals/hta-legislation/human-tissue-act-2004).

* 1. **Definition of Relevant Material**

The definition of Relevant Material in the Human Tissue Act 2004 (excluding human application) is:

Section 53: Relevant Material

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

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

*(a) embryos outside the human body, or*

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

To supplement the HTA's broader policy framework on Relevant Material, a list has been produced to provide stakeholders with guidance on whether specific materials fall within the definition of Relevant Material under the Human Tissue Act. The list is available on the HTA website: [List of materials considered to be ‘relevant material’ under the Human Tissue Act 2004.](https://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004/list-materials)

* 1. **HTA Directions**

Under the HT Act, the HTA has the power to issue its expected standards (or Directions) to establishments. This means that the HTA can issue general Directions to establishments to take into account changes in policy and legislation. The HTA may also make Directions that are specific to a particular establishment.

* 1. **HTA Codes of Practice and Guiding Principles**

The HTA Codes provide interpretation of the HT Act and HTA Directions and give practical guidance to support good practice in important areas of science and medicine.

The HTA Codes are detailed in the list below. The most up to date HTA Codes, and associated licensing standards and guidance, should be downloaded from the HTA website: [HTA Codes, standards and guidance](https://www.hta.gov.uk/guidance-professionals/codes-practice). In addition, the MRC have produced a series of human tissue legislation summaries in collaboration with the HTA: [MRC guidance for using human samples in research](https://www.ukri.org/councils/mrc/facilities-and-resources/find-an-mrc-facility-or-resource/mrc-regulatory-support-centre/using-human-samples-in-research/).

The HTA Codes are incorporated by reference into the University’s Code. All staff and students involved in activities involving Relevant Material are responsible for reading and applying the University Code.

|  |  |
| --- | --- |
| Code of Practice | Topic |
| A | Guiding principles and the fundamental principle of consent |
| B | Post-mortem examination |
| C | Anatomical examination  |
| D | Public Display  |
| E  | Research  |
| F | Donation of solid organs and tissue for transplantation  |
| G | Donation of allogeneic bone marrow and peripheral blood stem cells (PBSCs) for transplantation  |
|  | Human Transplantation (Wales) Act 2013 |

The HTA’s existence and approach are founded on four guiding principles. These principles are derived from the HT Act, explicitly or implicitly, and actively inform the HTA’s overall approach to regulation, Codes of Practice and licensing standards. The principles should inform the actions of anyone involved in using materials originating from people, and therefore anyone undertaking activities falling within the remit of the HTA must give them due regard. Where the principles refer to tissue, they apply equally to entire organs.

The Guiding principles are listed below and further information about them is available in Code of Practice A:

* consent
* dignity
* quality
* honesty and openness
	1. **Stem Cells**

If you intend to work with human stem cells the Research and Human Tissue Manager should be contacted for advice.

* 1. **HFEA**

If you intend to work with human gametes (ova or spermatozoa) or embryos (outside the body), while outside the definition of Relevant Material for the purposes of the Human Tissue Act 2004, these materials fall within the remit of the Human Fertilisation and Embryology Act 1990 and are regulated by the Human Fertilisation and Embryology Authority (HFEA). You should refer to, and comply with, the [HFEA Code of Practice](https://portal.hfea.gov.uk/media/1756/2021-10-26-code-of-practice-2021.pdf). Please contact the Research and Human Tissue Manager for advice.

# University arrangements for compliance with HT Act

1. **HTA licences**

An HTA licence (the “Licence(s)”) is required to store Relevant Material for Scheduled Purposes specified under the HT Act. Licences cover five sectors: human application; anatomy; post-mortem examination; research and public display. The University is the Licence Holder (the “LH”) and the LH representative is a member of the University senior management team.

A Licence is required to store Relevant Material for research unless a licence exemption applies. Most research involving Relevant Material at the University is undertaken with a favourable opinion from an NHS REC, this constitutes an HTA licensing exemption. Part C of this code of practice details how to work with Relevant Material under an HTA licensing exemption.

The University identified the need to license its activities and premises to comply with the HT Act. The University holds five Licences in relation to the premises listed in the following table. Each Licence has a Designated Individual (the “DI”) who is responsible for compliance with the HT Act:

|  |  |  |  |
| --- | --- | --- | --- |
| **Sector** | **Licence no** | **Premises** | **Designated Individual** |
| Anatomy | 12135 | School of Anatomy | Mrs Kate Sparey  |
| Research | 12200 | BristolDental School and Hospital | Dr Maria Davies |
| Research | 12248 | Biomedical Sciences Building | Dr Wael Kafienah |
| Research | 12273 | South West Dementia Brain Bank, Bristol Medical School | Dr Laura Palmer |
| Research | 12512 | Oakfield House, Bristol Medical School.Satellite Site: Langford House | Dr Susan Ring |

1. **Human Tissue Working Group**

The HTWG was established as an expert advisory group to share best practice in all aspects of the HTA licensing requirements. In addition, it functions as a forum for HT Act related consultations on behalf of the University. It includes a programme of internal audits of Licences held by the University. The HTWG meets not less than three times a year and is supported by the Research Governance Team. The HTWG reports to the University Ethics of Research Committee. Further information can be found on the [HTWG webpages](https://www.bristol.ac.uk/red/research-governance/human-tissue/university-arrangements/).

1. **Training**

Training in principles and application of the HT Act is available in different formats and is delivered by the Research Governance Team or DIs as appropriate. Tailored training is available upon request. It is strongly recommended that members of staff and students working with Relevant Material also complete the MRC and HRA e-learning courses:

[MRC e-learning](https://byglearning.com/mrcrsc-lms/course/index.php?categoryid=1)

[HRA e-learning](https://www.hra.nhs.uk/planning-and-improving-research/learning/e-learning/)

Staff and students involved in seeking consent must be specifically trained in the implications and essential requirements of taking consent.

Other useful resources include:

* [University guidance on General Data Protection Regulation](https://www.bristol.ac.uk/secretary/data-protection/gdpr/)

* [MRC resources for use of human samples in medical research](https://mrc.ukri.org/research/facilities-and-resources-for-researchers/regulatory-support-centre/human-tissue)

All staff and students working with Relevant Material must keep a record of the training they have received relevant to that work. (See appendix B for an example).

# What do I need to know about Licences and consent?

Where a member of the University’s staff or any students intend to undertake work or research involving the storage and use of Relevant Material from the living or the removal, storage and use of Relevant Material from the deceased they must consider the following:

1. whether there is a requirement to be licensed;
2. the requirements for consent.

Flow charts available in the [HTA Code E: Research](https://content.hta.gov.uk/sites/default/files/2020-11/Code%20E.pdf) will assist in determining Licence and consent requirements.

# Part B: working under a Licence

1. **Introduction**

Licences cover specific premises and are not University wide. You must store Relevant Material for Scheduled Purposes, e.g. research, only on HTA licensed premises unless an **exemption applies** (see Part C).

* 1. **Terms of Licence**

The University is the LH with defined responsibilities under the HT Act. The original Licences are held by the Research Governance Team.

Copies of Licences must be displayed at the licensed premises to which each Licence relates. It is the responsibility of staff and students to note the terms of the Licence, including any special conditions applicable to their area of activity.

* 1. **Licence fees**

Licence fees are paid annually, and current fees are displayed on the HTA website.

1. **The role of the Designated Individuals**

In relation to a Licence under the HT Act, a DI means the person under whose supervision the licensed activity is authorised to be carried on.

1. **Appointment and training of DIs**

The University’s Licences, DIs and licensed premises (including satellite sites) are listed in Part A of this Code of Practice and may also be found on the [HTWG webpages](https://www.bristol.ac.uk/red/research-governance/human-tissue/designated-individuals/). The Research and Human Tissue Manager will keep these details up to date. The appointment of individuals to the role of DI must receive prior approval from the HTA before the role is implemented. Heads of Schools (“HoS”) and/or outgoing DI must therefore notify the Head of Research Governance as early as possible of any intended changes to the role of the DI.

The HTA provides guidance on the required knowledge and competencies for DIs. Evidence of training should be held by the DI. (See Annex B for training record forms).

The University has a Risk Management Policy and Procedure for the assessment of University risks and includes, within the Impact Scoring Matrix, the impact of non-compliance with the HT Act. A new Research and Innovation Risk Register is being developed which will document this in more detail and will be owned by the PVC-Research and University Research Committee. Any situations that the HTWG consider might impact on this risk will be reported to the PVC-Research via the LH representative.

Where a DI is unable to discharge their duties, the LH representative may make an application to the HTA to vary the Licence in order to substitute another individual as DI. The LH representative will work closely with the HoS to put in place appropriate measures if a DI is temporarily unable to oversee licensable activities.

Persons Designated (PD) assist DIs with certain aspects of their role and should also be notified to the HTA and listed under each Licence. In addition, a Senior Person Designated (“SPD”) should be identified under each Licence. This is an internal University role and not a role specified or required by the HTA. The SPD will act as the primary contact for the LH representative in the absence of the DI and will be the first person to be considered for the role of DI should the DI be unable to discharge their duties. The SPD role could be supported by an appropriate person in each Licence who is familiar with the more technical aspects of the Licence. The Research and Human Tissue Manager must be informed of the names of these individuals.

It is the responsibility of the DI to notify the HTA and the LH representative of changes to PDs.

The HTA provides [guidance on licensing for DIs and LHs](https://www.hta.gov.uk/guidance-professionals/licences-roles-and-fees/licensing/licensing-under-ht-act/designated) on their website.

1. **Duties and qualifications of DIs**

Section 18 of the HT Act provides that it shall be the duty of the DI to secure:

1. *“that the other persons to whom the licence applies are suitable persons to participate in the carrying on of the licensed activity;*
2. *that suitable practices are used in the course of carrying on that activity*, *including the maintenance of records of stored Relevant Material;* *and*
3. *that the conditions of the licence are complied with.”*

The HTA has the power to revoke the University’s Licences if it is satisfied that a DI has failed to discharge (or is unable because of incapacity to discharge) their duties under section 18 of the HT Act.

A person should not undertake the role of DI unless they are in a position to discharge their duties under section 18. DIs need to have knowledge and understanding of the HT Act and the HTA Codes and they should demonstrate managerial capability, ensuring development and implementation of quality management systems and supervising responsibility to effect change. They should have time within their substantive role to carry out the responsibilities of a DI and to ensure compliance with licence conditions.

The University has recognised the role of DI as one of its leadership and management roles and it is remunerated accordingly.

Heads of School and Deans need to have a general understanding of the responsibilities of the DIs in their School or Faculty in order to ensure that the DI has the requisite authority and support from them to fulfil their duties under the HT Act and the HTA Codes.

1. **Authority of DIs**

Notwithstanding any formal line management responsibilities, DIs are authorised to give instructions and directions to students and staff, including staff more senior to themselves, as necessary in order to ensure compliance with the conditions of the Licence. Failure of staff or students to comply with such instructions and directions from a DI may result in the member of staff or student being forbidden to continue with an activity involving Relevant Material and may amount to misconduct or gross misconduct resulting in disciplinary action being taken against the member of staff or student. The University will support its DIs in the exercise of their authority in order to protect the DIs from criminal prosecution and to protect the University from loss of its licences and reputational damage.

A breach of a duty by a DI can result in serious penalties including fines and up to three years imprisonment. It is therefore important that clear lines of accountability exist between DIs and individuals who participate in a licensed activity for which that DI is responsible.

1. **Insurance and Indemnities for DIs**

*1. What is the extent of an individual DI’s personal liability?*

DIs are personally responsible for compliance with the HT Act on their HTA licensed premises.

Offences under the HT Act and the Regulations include:

* removing, storing or using Relevant Material for Scheduled Purposes, on unlicensed premises;
* removing, storing or using Relevant Material for Scheduled Purposes, without appropriate consent for that purpose;
* carrying out licensable activities without holding a licence from the HTA;
* failing to produce records or otherwise obstructing the HTA in carrying out its statutory responsibilities;
* storing Relevant Material with the intention of extracting and analysing the DNA without the consent of the individual from whom the Relevant Material came (with exemptions for medical diagnosis and treatment, and for criminal investigations).
* holding Bodily Material without the qualifying consent of the person concerned with the intention of extracting and analysing the DNA and using the results.

*2. What are the penalties for offences?*

Offences can be tried in a magistrates’ court or a Crown court and penalties range from a fine, to imprisonment for up to three years, or both.

*3. What insurance cover does the University provide to DIs?*

The University holds insurance that protects DIs against the cost of legal expenses up to the indemnity limit to defend themselves against prosecutions under the HT Act and the Regulations. This is known as “Directors’ and Officers’ Liability” insurance.

The insurance policy provides cover should any employee of the University be held personally liable for any *wrongful act* committed or alleged to have been committed by the employee in the course of *managerial or supervisory duties* for the University.

The insurers will pay for legal defence costs up to the point where a DI is either found guilty or advised to plead guilty to an offence plus any compensation awarded in a civil claim against the DI (e.g. for distress or hurt feelings due to tissue being stored without permission).

*4. What is not insured?*

The University is not permitted to insure against fines or penalties incurred by DIs as a result of criminal prosecution.

The University is not able to provide insurance for the physical holdings on licence, overseen by the DI.

*5. What do DIs need to do in cases of alleged offence under the HT Act?*

If you think that you may be held responsible for an alleged offence under the HT Act or the Regulations, you must contact the LH representative and University’s Insurance Manager immediately in order that your claim is notified to the insurers within the strict timescales that apply.

1. **Standards of compliance required by HTA**

Application for a Licence takes the form of a compliance report, which is completed on the HTA website. There is a version relevant to each sector but they all contain four common categories of standards that the HTA require applicants to assess and evaluate their performance against, as detailed in the [relevant HTA standards and guidance](https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/codes-practice). Since 2011 the DI is required to submit a biennial statement of compliance to the HTA. The categories are:

1. **Consent**

One of the main principles established by the HT Act is the requirement for appropriate and valid consent for Scheduled Purposes. You should refer to the consent requirements detailed in the HTA Code of Practice A (Guiding principles and the fundamental principle of consent) to determine if consent is required for the collection, storage and use of Relevant Material.

The consent standards require users of Relevant Material to be able to demonstrate that their processes for seeking and gaining consent comply with the HT Act and the HTA’s Codes of Practice. The standards also cover the documentation and information used to support the establishment’s consent procedures, and ensure that staff involved in seeking consent are suitably trained and equipped for the task.

Qualifying consent is required to analyse DNA derived from Bodily Material and to use the results. Bodily Material differs from Relevant Material as it includes hair and nails from the living and gametes. It also refers to processed material such as plasma, serum and saliva obtained by the use of collection kits which lyse cells prior to DNA extraction. This means that if appropriate consent to use Bodily Material has previously been obtained under the HT Act for a Scheduled Purpose, it is not necessary to obtain separate consent where that use also involves DNA analysis as long as the consent does not rule-out DNA analysis. However, where samples are being prospectively collected for research involving DNA analysis it should be made clear to the donor that their Bodily Material may be used for this purpose, if that is the intention, by, for example, including a reference to the intended DNA analysis in the consent form and participant information sheets.

Records must be kept by individual DIs of all licensable Relevant Material obtained by staff and students including evidence of consent (where applicable). It is the responsibility of the researcher, staff or student to keep a record of the whereabouts of signed consent forms and to make them available to the DI if asked. Anyone removing, storing or using Relevant Material in circumstances for which the HT Act requires consent must be personally satisfied that relevant consent is in place.

*Consent exceptions*

a. It is lawful for Relevant Material to be stored and used without consent for research purposes only if:

1. the tissue is from a living person; and
2. the research has a *current* favourable opinion from a recognised NHS Research Ethics Committee (NHS REC); and
3. the Relevant Material is anonymised and the researcher takes all necessary steps not to identify the person from whose body the Relevant Material has come.

b. The consent requirements of the HT Act are not retrospective. This means that legally it is not necessary to seek consent under the HT Act to store or use an ‘existing holding’ for research, however licensing requirements still apply. An ‘existing holding’ is Relevant Material from the living or deceased that was already held at the time the HT Act came into force on 1 September 2006.

c. Whatever the date the Relevant Material was donated for research, if more than 100 years have elapsed since a person’s death, consent to undertake research on their Relevant Material is not required under the HT Act. A licence is not required to store this Relevant Material.

d. The consent provisions of the HT Act do not apply to imported Relevant Material. However, it is good practice for there to be mechanisms in place to provide assurance that the Relevant Material has been obtained with valid consent. Licensing requirements still apply.

Consent may be specific, in relation to a defined project, or broader in its scope as generic consent, for example to allow storage and use of tissue for an as yet unknown research project or deposit in a research tissue bank. In practical terms, specific and generic consent may be sought at the same time, to derive the greatest benefit from valuable samples donated for research. Generic consent should be supported by safeguards and assurances for donors.

The HTA has developed model consent forms for [post-mortem examinations](https://www.hta.gov.uk/guidance-professionals/regulated-sectors/post-mortem/post-mortem-model-consent-forms) and [body donation](https://www.hta.gov.uk/guidance-professionals/regulated-sectors/anatomy/model-anatomy-consent-forms-and-body-donation), which are available on its website.

If the purpose of storage of Relevant Material from a living person is for research then information sheets and consent forms must follow the [HRA guidance](http://www.hra-decisiontools.org.uk/consent/examples.html).

Once obtained, consent forms must be filed as follows:

1. for a specific research study involving patients, in the patient’s clinical notes with a copy in the research study master file kept by the Principal Investigator
2. for a specific research study involving healthy volunteers, in the study master file
3. for tissue bank donations from patients, in the patient’s clinical notes with a copy in the tissue banks master file kept by the tissue bank manager.
4. for tissue bank donations from healthy volunteers in the tissue banks master file kept by the tissue manager.

In situations where a University HTA licence stores samples from a study whose ethical approval has expired, either:

a. copies of the original consent forms should be stored with the Relevant Material; or

b. where the individual consent forms are to remain with the other party the following reassurances should be provided and documented between the parties:

* confirmation that appropriate consent is in place, including a copy of the blank participant information sheet and/or consent form;
* confirmation that consent forms will not be destroyed while Relevant Material are still held by the University;
* confirmation that the University will be advised if consent is withdrawn so that Relevant Material may be destroyed;
* assurance that consent forms will be made available, at individual level consent (paper or electronic), in the event of a HTA inspection;

In the case of external parties this confirmation would be in the form of a Material Transfer Agreement or other appropriate contractual arrangement.

c. the transfer of samples onto a University HTA licence that are considered to be an ‘existing holding’ should be discussed with the Research and Human Tissue Manager to ensure appropriate consenting arrangements are documented.

An ‘existing holding’ is Relevant Material from the living or deceased that was already held at the time the HT Act came into force on 1 September 2006.

A record of the location of the consent forms/documented assurance of consent must be kept by the Principal Investigator/Tissue Bank Manager and they must be made available to the DI, Research Governance Team, monitors and/or regulators on request.

1. **Governance and Quality Systems**

It is essential to demonstrate that there is a suitable governance framework, underpinned by clear and controlled documentation, effective audit, staff training and organised record-keeping including an effective system of risk management and suitable systems to deal with adverse events. Each Licence must work within a defined quality system.

1. **Documentation required for the quality system**

The HTA require the recording of policies and procedures in a Quality Manual which must be identified by version number and managed by a document control system.

HTA guidance for sector specific requirements is available in the [relevant HTA standards and guidance](https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/codes-practice).

The Quality Manual should contain the documents necessary to demonstrate compliance with the relevant standards and include, but not be limited to, the following:

* Organisation chart listing staff roles and line management structure
* Internal audit schedules and audit reports
* Policies (e.g. consent incl. consent documentation, H+S, disposal, ethics, governance, adverse events, complaints)
* Standard Operating Procedures (SOP) including the template to guide the development of the SOP, Document control and storage of records
* Traceability records for Relevant Material including origin, storage, use, transfer and disposal
* Job descriptions, training records, including induction programmes
* Risk assessments for critical processes
* Adverse events and incidents log
* Complaints log
* Maintenance contracts, maintenance log, validation and calibration of critical equipment
* Contingency plans for equipment / site failure
* Meeting agendas and minutes including systems used to distribute local/national information
* Agreements e.g. contracts, Material Transfer Agreements, Service Level Agreements, Third Party Agreements
1. **Health and Safety**

Any work involving Relevant Material must be in line with the Safety and Health Services guidance, including completion of risk assessments as appropriate. Please refer to Annex A and B.

1. **Incident, Adverse Events and risk assessments**

*Incidents and Adverse Events*

Investigating incidents and Adverse Events (AEs) and taking corrective and preventive action is an important part of the risk management process. The purpose is to assure the health and safety of those handling Relevant Material and to avoid loss or damage to Relevant Material. Incidents or AEs that lead to or could have led to the harm of any individual(s) must be reported to Safety and Health Services. A record must be kept of all incidents and AEs together with the outcome of any investigation.

All establishments licensed by the HTA are required to have an internal system for reporting incidents and AEs and, where necessary, instigating an investigation or root cause analysis. This includes any ‘near-miss’ situations that have the potential to affect individual(s) or the Relevant Material itself.

DIs must have a process to ensure awareness of incidents and AEs so that proper investigation and reporting can take place. There should be an incident and adverse event SOP detailing how incidents and AEs are logged, reported, addressed and monitored.

There is currently no requirement for establishments in the research or anatomy sector to report incidents and AEs to the HTA but the HTA encourages DIs to seek further advice where necessary.

Relevant examples of incidents and adverse events include:

• specimen loss;

• missing or incorrect documentation;

• security breach;

• abnormalities in storage temperature readings;

• inappropriate disposal.

Following an incident or AE, advice should be sought at the earliest opportunity from the Research and Human Tissue Manager and/or the Head of Research Governance. Incidents and AEs, and regular updates thereof, should be reported to the HTWG functioning as the expert advisory group and to ensure lessons learned messages are available to all UoB DIs.

NHS REC approved studies should report Serious AEs to University Hospitals Bristol and Weston NHS Foundation Trust (UHBW) who manage adverse reporting on behalf of the University in line with a Service Level Agreement. Information should be included in the annual progress report to the NHS REC and other regulatory bodies (as appropriate). A record of Adverse Events should be held in the Study Master File.

*Risk assessments*

There are a number of circumstances that could result in loss or damage to Relevant Material, which should be subject to risk assessment. These may include:

* 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;
* storage of anatomical specimens and contingency arrangements;
* loss of or damage to human tissue/specimens;
* sample mix-up or loss of traceability;
* transport of specimens to and from the establishment ;
* security arrangements
* incorrect/inappropriate disposal

This section of the Code of Practice should be read in conjunction with the following documentation:

* [Health and safety policies, responsibilities and organisation](http://www.bristol.ac.uk/safety/media/gn/safety-organisation-gn.pdf)
* [University Safety and Health Services policies and guidance](http://www.bristol.ac.uk/safety/policies/)
* [University/local policy guidance on lone working](http://www.bristol.ac.uk/safety/media/gn/lone-working-gn.pdf)
* Licence exit strategy
* Any relevant regulatory alerts from the HTA
1. **Internal audits**

The University has initiated an internal audit programme of its licensed premises. DIs will cross audit other licensed premises in accordance with this programme. The audit programme can be found on the [HTWG webpages](https://www.bristol.ac.uk/red/research-governance/human-tissue/inspections-audits/).

The objectives of the internal audits will be to:

* ensure the activities on the premises comply with the HT Act, the Regulations and HTA Codes;
* identify good practice that could be shared with others;
* identify practices that should be changed or improved with a plan for corrective and preventative actions that includes training and resource requirements.

Where possible the audits will mirror HTA inspections in terms of process and scope. The closure and progress against actions arising from the internal audit is managed by the Research Governance Team and reported to the HTWG.

Reports of the internal audits will be sent to the LH representative, Chair of the HTWG, the HoS and the Dean of the Faculty within which the audited premises are situated. Recommendations will be clearly identified, indicating which recommendations may require additional financial resources. The Pro-Vice Chancellor (Research) will receive a copy for information.

1. **HTA inspections**

As part of its regulatory function the HTA carries out inspections of licensed premises. In the majority of cases, the University will have due notice of an inspection; but the HTA may carry out unannounced inspections. There is no specific schedule for the inspection of Licences. These inspections will, in the main, be risk based or may be triggered by an incident or AE. Following an inspection, the HTA will write a report specifying any non-compliance that must be corrected. The report may also include advisory recommendations. The closure and progress against actions arising from an inspection is managed by the Research Governance Team and reported to the HTWG. If the report recommends the addition or removal of licence conditions, an HTA licensing panel will review the report to determine whether the licence should be varied or revoked.

1. **Traceability**
2. **Traceability and records of stored Relevant Material**

Full traceability for the human material for which DIs are responsible, from receipt to final disposal/disposition needs to be demonstrated. HTA inspectors will test this through traceability audits carried out on site. There is an expectation of a pro-active approach to assuring effective traceability throughout the lifetime of the Licence. In addition, as the final traceability step, disposal arrangements need to be in place that are in accordance with the HTA’s Codes. Traceability of Relevant Material is essential, and records must be kept documenting the storage, use and disposal of Relevant Material. Complete and up to date records will need to be available for both internal audit and external inspection by the HTA.

The relevant DI is responsible for ensuring records are adequate and appropriate with reference to the guidance contained in the relevant HTA Codes.

Records may be in an electronic format (e.g., spreadsheets or databases) or as paper records, with information about (including testing of) a backup system in case either type of record is jeopardised.

Access controlled core information required is:

* The origin of Relevant Material and date acquired
* Whether Relevant Material is:
	+ held with consent;
	+ held under Licence or stored for a defined project under NHS REC favourable opinion;
	+ from a living or deceased donor;
	+ imported
	+ anonymised
* Number of samples, description of sample/cell type and storage details including location
* Licence number or NHS REC reference, date of REC expiry and Principal Investigator
* Date and details of use, transfer (including copy of Material Transfer Agreement) and disposal

Staff and students using Relevant Material with authorised access are required to make and amend entries in the records kept by the relevant DI and to keep them up to date and accurate.

1. **Transfer of Relevant Material and / or disposal**

Whenever Relevant Material for Scheduled Purposes is transferred internally or externally it must be documented.

1. Internally – the transfer and subsequent storage, use and disposal of Relevant Material must be governed by a SOP and internal transfer agreement.
2. Externally - the transfer and subsequent storage, use and disposal of Relevant Material must be governed by a Material Transfer Agreement (the “MTA”) approved by the Research and Enterprise Division (RED). For NHS REC studies, the inclusion of sample transfer should be documented within the ethically approved documentation and be accompanied by an MTA for the transfer of Relevant Material outside of the University.

A standard University MTA is in place for transferring Relevant Material to individuals or organisations outside the University. Please contact the Research and Human Tissue Manager in RED or further information.

The import (Relevant Material received from outside of England, Wales and Northern Ireland are considered an import) of Relevant Material must follow the HTA Code of Practice. Prior to import individual guidance must be obtained from the Research and Human Tissue Manager.

1. **Disposal**

For detailed guidance on disposal of Relevant Material refer to the [University’s Disposal Policy](http://www.bristol.ac.uk/red/research-governance/human-tissue/resources/):

1. **Premises, Facilities and Equipment**

The University must demonstrate that premises and facilities are appropriate for licensed activities and are safe, secure and clean. In addition, establishments will have systems for on-going monitoring to ensure all key quality specifications are maintained. These standards also cover equipment, ensuring that it is appropriate, and suitably maintained, and that it does not present an impediment to the staff using it.

# Part C: Working under an HTA licensing exemption

1. **Introduction**

A Licence is required to store Relevant Material for research unless a licence exemption applies. This section details how to work with Relevant Material under an HTA licensing exemption. If you are working under a Licence please refer to Part B.

Most research involving Relevant Material at the University is undertaken with a favourable opinion from an NHS REC, this constitutes an HTA licensing exemption. Researchers should manage samples in line with specifications made in the protocol and ethics application. This includes record keeping, sample transfer, adverse event reporting and disposal. Further information on good practice in these areas is available in Part B, especially if you are considering moving Relevant Material onto a Licence at the end of the study.

1. **Setting up a new study**

Research that involves the storage, collection, use and/or import of human tissue to include Relevant Material (paragraph 79 of Code E) requires an ethical review by an NHS REC. This includes research involving healthy volunteers on non-NHS premises. University ethics committees are not recognised under the Human Tissue Act. Dual ethics review is not required and should be avoided.

The Human Tissue Act requires that consent must be sought for the removal, storage and use of human tissue for Scheduled Purposes, e.g. research, subject to the exceptions set out in Part B, 3a of this Code.

In addition:

- If the intention is to collect Bodily Material with the aim of DNA analysis, consent for this purpose must be obtained at the start of the study (see below).

- If there is an intention to store samples beyond the life of a study consent for future storage and use should be taken at the start of the study.

There are circumstances where a favourable opinion from a University ethics committee can be obtained with prior agreement of the Research Governance Team.

Possible scenarios for seeking University ethics review and working under an HTA licensing exemption:

1. researchers will hold the Relevant Material temporarily and for no longer than a week prior to transporting the samples elsewhere; or
2. researchers will hold the Relevant Material for no longer than a week where there is no intention to use or store cellular material for research, and the only holding of cellular material is temporary and for the purpose of obtaining material which does not contain cells

**Please note**:

The HTA Code indicates that studies which plan to collect samples that are Relevant Material and store them solely for the purpose of research within the week timeframe e.g. processing a blood sample and analysing in that week require a HTA licence, or NHS REC review so that the study works under a HTA licence exemption (N.B. sample analysis of Relevant Material immediately upon collection is fine as no storage is planned). Please contact the Research and Human Tissue Manager to confirm the appropriate governance pathway.

*DNA analysis*

Qualifying consent is required to analyse DNA. This means that if consent to use Bodily Material has been obtained under the HT Act for a Scheduled Purpose such as research, it is not necessary to obtain separate consent where that use also involves DNA analysis. However, it should be made clear to the donor that their Bodily Material may be used for this purpose, if that is the intention (adapted from the HTA Code of Practice on research), by, for example, including a reference to the intended DNA analysis in the consent form and participant information sheets.

*Import of Relevant Material*

If you are obtaining Relevant Material from outside England, Wales and Northern Ireland this is considered an import. Storage of imported Relevant Material for research is a licensable activity under the HT Act and will either need to be stored under a HTA licence or favourable opinion from an [NHS REC](http://www.bristol.ac.uk/red/research-governance/ethics/nhs-ethics/index.html) (preferred option). This is the case even if the Relevant Material has been collected with ethical approval in the country of origin. Imported material should be procured, used, handled, stored, transported and disposed of in accordance with the consent given by the person from whom it came. In addition, UoB should satisfy itself, with due assurance from the partners abroad, that any Relevant Material intended for import is sourced consistently with the legal and ethical review requirements in England, Wales and Northern Ireland. The Research and Human Tissue Manager should be contacted prior to the import taking place.

1. **Working with healthy volunteers (including colleagues or students)**

If you are considering the collection of Relevant Material or Bodily Material from healthy volunteers (including colleagues or students), you are reminded that this research has the same legal and ethical standards as would be applicable to any other participant in research. Your research must be reviewed by an ethics committee. If the review is undertaken by an NHS REC (preferred option) your research will be exempt from licensing requirements. If the review is undertaken by a University REC (with the agreement of the Research Governance Team) the Relevant Material must be stored and used on licensed premises in line with Part B of this code (above) with the explicit permission of the DI.

Valid and freely given consent must be obtained from healthy volunteers. This includes giving information on what samples will be used for, the risks of discovery of health-related findings and how these would be handled, how their privacy will be protected and their right to withdraw.

Further guidance is available from the Research and Human Tissue Manager and the following resources should be read prior to collecting Relevant Material from healthy volunteers:

* [MRC ethics series Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines (2014)](https://www.ukri.org/wp-content/uploads/2021/08/MRC-0208212-Human-tissue-and-biological-samples-for-use-in-research.pdf)
* [MRC Regulatory Support Centre: Guidance for staff asked to volunteer blood and/or other samples for research](https://www.ukri.org/wp-content/uploads/2021/11/MRC-291121-GuidanceForStaffAskedToVolunteerSamples.pdf) (2012)
1. **Procurement and subsequent transplant for research**

If your project involves the procurement and subsequent transplantation of Relevant Material for research, then you need to ensure that the NHS Trust holds an appropriate Licence.

1. **Working with tissue from a Research Tissue Bank**

If you are obtaining Relevant Material from a Research Tissue Bank (“RTB”) (sometimes called a biobank) for use in your research, you:

* should check the ethical arrangements of the RTB to determine whether your study will be covered by the RTB’s ethics approval or whether you need to make your own project-specific ethics application;
* should register the study with the Research Governance Team (where Relevant Material is obtained from an RTB external to UoB);
* must ensure that any terms and conditions are reviewed by the Research Contracts team in RED and any agreements/contracts with the RTB are signed by an authorised signatory (where Relevant Material is obtained from an RTB external to UoB);
* should be aware of your obligations on completion of the research using Relevant Material from an RTB.
1. **Setting up a Research Tissue Bank**

Setting up a new research tissue bank can have considerable resource implications for the Principal Investigator and the HTA licence it runs under. Therefore, funding for the set up and the plans to ensure the bank will remain sustainable in the future will be considered when ascertaining if this is a suitable option.

If you would like to explore the possibility of setting up an RTB you should contact the Research and Human Tissue Manager as early as possible.

1. **End of study and sample management**

If a study is carried out with a favourable opinion from an NHS REC researchers have the following options at the time when the ethical approval nears the date of expiry:

* If the project requires more time for completion the NHS REC and Research Governance Team should be notified of the intention to extend the duration of the ethical approval by completion of the HRA amendment tool.
* If a new study idea has been generated using the same Relevant Material, a new ethics application should be submitted prior to expiry of the current study. You need to check that consent is in place for future use of the Relevant Material.
* If the Relevant Material has no further use it should be disposed of in accordance with the details given in the ethics application form, the HT Act and [University Disposal Policy for Relevant Material](http://www.bristol.ac.uk/red/research-governance/human-tissue/resources/).
* If none of the above are possible options and the Relevant Material is felt to be valuable, please contact the Research and Human Tissue Manager who will assess the feasibility of depositing it in an RTB or storing it under an HTA licence. A number of checks will be undertaken to determine the suitability of each option. There is usually an application process for depositing samples into an RTB and there is a formal audit process for moving samples onto Licence.

If there is an intention to store samples beyond the life of a study then good practice biobanking guidelines should be followed from the start of the study, please contact the Research and Human Tissue Manager for further information:

Further information can be found in the following resources:

* [MRC ethics series Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines (2014)](https://www.ukri.org/wp-content/uploads/2021/08/MRC-0208212-Human-tissue-and-biological-samples-for-use-in-research.pdf)
* [MRC ethics series Good research practice: Principles and guidelines (2012)](https://www.ukri.org/wp-content/uploads/2021/08/MRC-0208212-Good-research-practice_2014.pdf)

If after reading the section above, you have established that it is unlikely that you are able to work under a Licence exemption and you believe that you may require a Licence you should contact the Research and Human Tissue Manager.

# Part D: Further advice and guidance

In the first instance please contact the Research and Human Tissue Manager or the Head of Research Governance for advice in relation to the HT Act. Concerns and problems may be referred to the HTWG or to the LH representative for resolution.

**Contact details:**

Research and Human Tissue Manager

research-governance@bristol.ac.uk,

Head of Research Governance

Adam.Taylor@bristol.ac.uk,

**Useful links:**

[University of Bristol human tissue webpages](http://www.bristol.ac.uk/red/research-governance/human-tissue/)

[University of Bristol Regulations on Research misconduct](https://www.bristol.ac.uk/applicants/media/policy-documents/2018/undergraduate/research-misconduct-regulations.pdf)

[Human Tissue Authority](https://www.hta.gov.uk/)

[HTA Codes of Practice, standards and guidance](https://www.hta.gov.uk/guidance-professionals/codes-practice-standards-and-legislation/codes-practice)

[HTA definition of Relevant Material](https://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004/list-materials)

[HTA licensing information](https://www.hta.gov.uk/guidance-professionals/licences-roles-and-fees/licensing)

[Human Fertilisation and Embryology Authority (HFEA)](https://www.hfea.gov.uk/)

[MRC resources for use of human samples in medical research](https://www.ukri.org/councils/mrc/facilities-and-resources/find-an-mrc-facility-or-resource/mrc-regulatory-support-centre/using-human-samples-in-research/)

[MRC human tissue legislation summaries](https://www.ukri.org/publications/research-and-the-human-tissue-act-2004/)

[MRC ethics series Human Tissue and Biological Samples for Use in Research: Operational and Ethical Guidelines (2014)](https://www.ukri.org/wp-content/uploads/2021/08/MRC-0208212-Human-tissue-and-biological-samples-for-use-in-research.pdf)

[MRC ethics series Good research practice: Principles and guidelines (2012)](https://www.ukri.org/wp-content/uploads/2021/08/MRC-0208212-Good-research-practice_2014.pdf)

[MRC Guidance for staff asked to volunteer blood and/or other samples for research (2012)](https://www.ukri.org/wp-content/uploads/2021/11/MRC-291121-GuidanceForStaffAskedToVolunteerSamples.pdf)

[Health Research Authority](https://www.hra.nhs.uk/)

Version Control

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| --- | --- | --- |
| VERSION | REASON FOR THE CHANGE | DATE |
| 1 |  | 02/03/2009 |
| 2 | Addition of RTB section | 10/09/2009 |
| 3 | Routine updates and addition of: options upon expiry of ethical approval; research with healthy volunteers; research with stem cells | 23/11/2010 |
| 4 | Routine updates and addition of: Langford satellite site and regular compliance returns to the HTA | 21/05/2012 |
| 5 | Routine updates, clarifications and addition of: additional information on research involving Relevant Material, training and inclusion of health and safety information and training record form previously detailed in Induction pack | 10/12/2013 |
| 6 | Routine updates and clarifications. Restructure to create specific sections for working under HTA licence or HTA licencing exemption. | 24/4/2015 |
| 7 | Inclusion of new HTA Codes of Practice (wef 3/4/17); routine updates; licence infrastructure changes | 29/3/2017 |
| 8 | Routine updates; licence infrastructure changes | 28/11/2019 |
| 9 | Routine updates | 06/04/2022 |

# Annex A: Health and Safety guidance for working with Relevant Material

A wide range of biological materials are handled within the University and there is substantial variation in the types of hazards associated with them. University policy and guidance information sets out the systems in place for managing the risk from biological materials (biorisk) when used in University activities. These cover human health and safety, environmental protection and biosecurity and describe your obligations when handling biological material. The University also requires that anyone working with biological material registers their details via the Safety and Health Services website (http://www.bristol.ac.uk/safety/staff/biosafety/).

One of the main factors to consider in your risk assessment before obtaining and then working with human tissue is that pathogens may be present in the material, because of the distribution of specific pathogens within the body and the likelihood that they will be present due to the health status of individual donors or the specific patient group, or because of endemic or pandemic disease where and when the samples are sourced.

All work involving primary human material must be undertaken at a minimum of containment level 2 (see box). Your risk assessment must determine whether this is sufficient or whether a higher level of containment or additional measures are required because of an increased exposure risk or more severe infection risk. Any national guidelines must also be considered. The University therefore requires that all risk assessments for work with human material are registered with the University Biological and Genetic Modification Safety Committee, which must review and agree with the outcome of the risk assessment before work can commence. Further details of this committee and these procedures can be found on the Safety and Health Services website and in University policies and guidance ([https://www.bristol.ac.uk/safety/staff/biosafety).](https://www.bristol.ac.uk/safety/staff/biosafety) The University Occupational Health Service website also has information on actions to take if an accidental exposure to a human pathogen is suspected (<http://www.bris.ac.uk/safety/occupational-health/contact/needlestick-hotline/>).

**Containment Levels** - work with biological materials is undertaken in containment laboratories and using good microbiological practice, occupational health, and hygiene. There are four levels of containment described in legislation and supporting guidance that are applied to laboratory design and operation in the UK (levels 1 to 4) with containment level 1 being the most basic and only suitable for work where it is certain that no pathogens will be worked with. The level of containment required for a work activity is determined as part of the risk assessment process. Further information is available in the guidance ‘Good microbiological practice and containment’ from <http://www.bris.ac.uk/safety/staff/biosafety/>.

**Health and Safety training and competence**

Before you can undertake tasks involving biological material you must be competent to do so. Your line manager must identify the required knowledge and skills required and assess your competence against these. You must be provided with sufficient instruction, supervision, training, and refresher training to develop and maintain the range of skills you will require during your work. This is a continual process for everyone and should involve frequent open conversations between you and your line manager to assess and identify on-going training needs. Online training modules are available to provide core training for people working with hazardous biological material. There are mandatory and optional modules depending on your work. For example, Module 1, Induction into biorisk management, is mandatory for anyone working with human material. Further information is available at <http://www.bristol.ac.uk/safety/staff/training/>

You will be required to be familiar with relevant documentation, such as codes of practice, risk assessments and operating procedures, and undergo the training relevant to your work. This will help ensure that you can carry out your work in a safe manner and, if appropriate, in accordance with the principles of the HT Act and the terms of any HTA licences that you will be working under. Training requirements will be determined by your supervisor and DI (if appropriate) considering University policy requirements, local risk assessments and HTA licence conditions.

A checklist or similar document (example in Annex B) should be used to ensure that the competency requirements are being assessed and met and this should be maintained as part of your overall training record. This record may be requested during University audits of your work or facilities or during inspections by external regulatory authorities such as the Human Tissue Authority or Health and Safety Executive.

|  |  |  |  |
| --- | --- | --- | --- |
| Record for (name) | BGMSC worker registration # | Activity (or activities) | Supervisor(s) and DI |
|  |  |  |  |

# Annex B: Competency and training record

The following template should be amended as required and maintained by the principal investigator/supervisor for the activity and be readily available for consultation by all parties and inspectors. The record should show initial capabilities, confirm the skills attained and practical tasks that can be undertaken with the level of supervision required stated where necessary. Some practical tasks may not be undertaken by everyone and some knowledge may also be acquired concurrently (e.g. school induction may include reference to safety responsibilities; risk assessments will contain hazard information for micro-organisms etc.). This information should be reflected here. This document should be reviewed and updated as competencies are acquired and as part of an annual staff/student appraisal process. A copy of the document should be given to the individual if they leave the laboratory and a copy also retained by the principal investigator for future reference.

| Criteria | Evidence (theoretical and/or practical) and other notes (e.g. further supervision requirements) | Reason for assessment (new task/refresher etc) | Worker Signature | Assessor signature | Date |
| --- | --- | --- | --- | --- | --- |
| **Core** |  |  |  |  |  |
| School induction  |  |  |  |  |  |
| School rules |  |  |  |  |  |
| Safety responsibilities  |  |  |  |  |  |
| **Safety training:** |  |  |  |  |  |
| * Online biorisk training module 1 (mandatory) and \_\_\_\_\_\_\_\_\_\_\_\_
 |  |  |  |  |  |
| * Genetic Modification
 |  |  |  |  |  |
| * Risk assessment (as appropriate)
 |  |  |  |  |  |
| * Others (please list):
 |  |  |  |  |  |
| **External training:** |  |  |  |  |  |
| HTA training |  |  |  |  |  |
| MRC Research and Human Tissue Legislation module |  |  |  |  |  |
| **Policies/guidance** |  |  |  |  |  |
| University Biorisk policies and procedures |  |  |  |  |  |
| University Human Tissue Code of Practice |  |  |  |  |  |
| **HTA documents:** |  |  |  |  |  |
| Codes of practice |  |  |  |  |  |
| **Risk assessments relevant to work/laboratory:** |  |  |  |  |  |
| * \_ \_ \_ \_ \_ \_(PI to list)
 |  |  |  |  |  |
| Laboratory experience |  |  |  |  |  |
| Good microbiological practice (**theoretical/practica**l) |  |  |  |  |  |
| Laboratory rules  |  |  |  |  |  |
| **Standard Operating Procedures:** |  |  |  |  |  |
| * \_ \_ \_ \_ \_ \_(PI to list)
 |  |  |  |  |  |
|  |  |  |  |  |  |
| Laboratory testing/maintenance requirements |  |  |  |  |  |
| Laboratory inspection requirements |  |  |  |  |  |
| Waste decontamination and disposal (**theoretical/practical**) |  |  |  |  |  |
| Emergency procedures including spill management and accident/incident reporting |  |  |  |  |  |
| Biosecurity |  |  |  |  |  |
| Carriage of Dangerous Goods (if relevant) |  |  |  |  |  |
| Others (please list): |  |  |  |  |  |
| **Equipment operation (practical):** |  |  |  |  |  |
| * room ventilation system
 |  |  |  |  |  |
| * storage alarms
 |  |  |  |  |  |
| * centrifuges
 |  |  |  |  |  |
| * microbiological safety cabinets
 |  |  |  |  |  |
| * \_ \_ \_ \_(other, PI to specify)
 |  |  |  |  |  |
| **Task or activity -specific skills and knowledge** |  |  |  |  |  |
| Please list: |  |  |  |  |  |
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