University Hospitals Birmingham
NHS Foundation Trust

CONTROLLED DOCUMENT

Policy on Human Tissue in Research

CATEGORY:	Policy
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PURPOSE	To set out how human tissue samples are to be collected, stored and used for research within the Trust
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1. Policy Statement and Objectives

This policy sets out how human tissue samples are to be collected, stored and used for research within the Trust. This will be achieved through the following objectives which ensure the Trust complies with the Human Tissue Act 2004 and International Conference on Harmonisation Good Clinical Practice guidelines.

1.1. **Consent**: Informed consent is obtained prior to collecting and storing human tissues samples for use in research.

1.2. **Traceability**: A record must be made by all staff taking a tissue sample for research purposes.

1.3. **Licensing**: Where required by law, all human tissue for research is collected, stored and, when appropriate, used under a licence applicable to that tissue, in compliance with the Human Tissue Act and Codes of Practice.

1.4. **Ethical Approval:** All research studies collecting, storing or using relevant material for research must have Research Ethics Committee (REC) approval in place.

1.5. **Accessing relevant material from the deceased:** Relevant material removed from the deceased is done in accordance with the appropriate licence and in compliance with the Human Tissue Act and Codes of Practice.

1.6. **Implementation and monitoring:** All activities involving human tissue in research are conducted within the framework of ratified, documented and up-to-date policies and procedures covering all licensable activities which have a documented system of audit in place.

2. Scope

2.1. The policy is relevant to any activity in the Trust involving human tissue that will be used for research purposes. The policy applies to all members of staff including students, locums, bank and agency staff and staff employed on honorary contracts who are involved at any stage of using human tissue in research process.

3. Definitions

Term	Definition
ATMP	Advanced Therapy Medicinal Products
DNA	Deoxyribonucleic Acid

HBRC	Human Biomaterials Resource Centre
HTA	Human Tissue Authority
MHRA	Medicines and Healthcare Products Regulatory Agency
NHSBT	NHS Blood and Tissue
NHS	National Health Service
ODT	Organ Donation and Transplant
RD&I	Research Development & Innovation
REC	Research Ethics Committee
RRK number	A reference number issued by R&D in order to trace research through Trust oversight systems
SNOD	Speciality Nurses in Organ Donation
SWBH	Sandwell and West Birmingham Hospitals NHS Trust

4. Legal Framework

The use of human tissue in research is governed through a variety of rules and regulations. The main legal framework is the Human Tissue Act (2004) (the "Act"). The Human Tissue Act applies to the removal, storage and use of relevant material for scheduled purposes in England, Wales and Northern Ireland.

5. Assurance Provision

Assurance regarding compliance with this policy, for all activities that are conducted under the exemption to licensing for research, will be provided by the Head of Research Governance, as set down in their duties. Assurance regarding compliance with this policy, for all activities of research carried out under HTA licences, will be provided by Designated Individuals (Appendix A). This will take the form of a compliance report summarising the information set down in the monitoring criteria in Appendix B.

6. Policy Framework and Standards

6.1. Main Principles

6.1.1. The main principle underlying the research component of the Act is that human tissue samples are donated for research – either a specific research study or for generic research. Samples are not donated to an individual, organisation or institution. This means that individuals, organisations and institutions are not free to do whatever they like with the samples and they do not legally own the samples.

6.1.2. The establishment of the Human Tissue Authority (the "HTA") was set out in the Act. The HTA is responsible for overseeing implementation of the Act and was tasked with producing a set of Codes of Practice. In particular, Code of Practice E relates to the use of human tissue in research.

6.1.3. There are separate regulations where cellular material derived from human tissue may be used for therapeutic purposes (the Human Tissue (Quality and Safety) Regulations 2007).

6.2. Relevant Material

6.2.1. The Act is concerned with regulating activity involving Relevant Material. This is defined as "… any material, other than gametes, which consists of, or contains, human cells."

6.2.2. Embryos outside the human body, hair, nail and extracted DNA are not Relevant Material, but they are included in an expanded definition of Human Biomaterial.

6.2.3. Blood plasma, serum and urine may contain human cells and are considered Relevant Material until processed to acellularity and the residual cellular material has been discarded.

6.2.4. A cultured human cell line is Relevant Material for as long as it is likely still to contain original cells from the person who donated them. Once the cell line has been established and is unlikely to contain original cells, then it is no longer regarded as Relevant Material.

6.2.5. The Act also covers activity that involves extraction of DNA from Bodily Material (which includes all Relevant Material plus embryos, hair and nail).The Act applies differently depending on whether tissue samples are collected and used for a specific research study or for generic research.

6.2.6. Note any data arising from DNA analysis may be personal data which is covered by the Data Protection, Confidentiality and Disclosure Policy, Consent to Examination or Treatment Policy and the Data Protection Act 2018.

Standard 1 – HTA C1 (a)(b)&(d)
Informed consent, where applicable, is obtained prior to the storage and use of human organs and tissue for research. ***Monitoring 1-2***

6.3. Tissue collection (Consent)

6.3.1. Subject to the exceptions below, there must be explicit consent to collect human tissue for research.

6.3.2. Tissue may be collected for storage and use in research without consent provided if:

(a) It is not reasonably likely that the researcher using the samples would be able to identify the person from whom the samples were taken; and

(b) The specific research study for which the samples are to be used has been approved by an NHS Research Ethics Committee (or is covered by the ethics approval for an HTA-licensed tissue bank); and

(c) The person from whom the samples were taken was alive at the time the samples were taken.

6.3.3. Imported material is not subject to the consent provisions of the Act, but it is regarded as good practice for there to be mechanisms in place to provide assurance that the tissue has been obtained with valid consent.

6.3.4. Notwithstanding points 6.3.1 and 6.3.2 above, a key principle of the Act is that, wherever possible, there should be consent to collect samples to use for research.

6.3.5. Consent to collect samples for a specific research study should be obtained using a study-specific information sheet and consent form that has been approved by an NHS Research Ethics Committee as part of the overall review of the research study. An alternative is possible for samples collected under the auspices of the University of Birmingham's Human Biomaterials Resource Centre (HBRC) in which case the Trust's standard "Consent to Examination or Treatment" form may be used.

6.3.6. If it is likely that some tissue samples may remain at the end of the initial research study and it is intended that these could be used for further research, then the initial consent form should include an option to use samples for future ethically approved, unspecified research. Otherwise re-consent will be required to use the samples for another study, before the original study's REC approval expires.

6.4. Surgical Consent Form

6.4.1. Residual human tissue, generated from a surgical procedure, or taken for diagnostic purposes which would otherwise be discarded, may be used for research provided there is explicit consent from the patient.

6.4.2. For this purpose the Trust's standard "Consent to Examination or Treatment", often referred to as the Surgical Consent Form contains an option for patients to consent to the use of discarded tissue for generic research.

6.4.3. The Surgical Consent Form can be used only to collect residual tissue after an appropriate surgical procedure or collection of blood samples for diagnosis.

6.4.4. The Surgical Consent Form should not be used to collect samples for a specific research project unless this process has been approved by an NHS Research Ethics Committee or the samples are collected under arrangements covered by the ethics approval for an HTA-licensed Human Tissue Bank.

6.4.5. Except for samples collected under the auspices of the HBRC, the standard Surgical Consent Form should not be used if additional samples are needed during a standard procedure or if an additional procedure is required specifically to obtain tissue samples for research. In these circumstances an ethically approved, study-specific information sheet and consent form must be used.

6.4.6. The discussion with the patient about collecting, storing and using the tissue samples for research must be recorded in the patient's medical records.

6.4.7. Written consent from relatives or legal representatives is always required to take relevant material from the deceased for research purposes (see section 6.19).

6.5. Existing Samples

6.5.1. It is permissible to use existing samples stored in an NHS diagnostic laboratory without consent provided that:

(d) It is not possible for the researcher using the samples to be able to identify the person from whom the samples were taken; and

(e) The specific research study for which the samples are to be used has been approved by an NHS Research

Ethics Committee (or is covered by the ethics approval for an HTA-licensed tissue bank); and

(f) The person from whom the samples were taken was alive at the time the samples were taken.

6.5.2. HBRC staff are able to collect samples from Trust laboratories for studies approved by the HBRC review committee that fall within the scope of the NHS ethics favourable opinion for the HBRC.

6.5.3. Samples collected specifically for research cannot be stored in NHS or University diagnostic laboratories unless the laboratories are covered by an HTA research licence.

6.5.4. Diagnostic laboratories cannot advertise themselves as a resource for researchers unless they hold an HTA research licence.

6.5.5. None of the diagnostic laboratories in the Trust currently (December 2020) hold HTA research licenses so they are not able to hold Relevant Material collected for generic research, nor may they advertise themselves as a resource for researchers (See Appendix A for list of current HTA licences)

6.6. Existing Holdings

6.6.1. The Act defines Existing Holdings as Relevant Material that was obtained before the Act came into effect (September 2006).

6.6.2. The consent provisions of the Human Tissue Act do not apply retrospectively. This means that it is not a legal requirement to obtain consent to store or use for research samples that were collected prior to the Act coming into effect. Approval from an NHS Research Ethics Committee is still required though for samples collected prior to September 2006.

6.6.3. However, the HTA recommends that “If practical, the consent of the participant should be sought and the views of the deceased person or of their family (if known) must be respected”.

6.7. Transplantation

6.7.1. Tissue that has been removed from a deceased person for the purposes of transplantation but proves not to be suitable, may be used for research provided there is consent from the relatives or legal representative, or the source of the tissue is not identifiable by the researcher and it is to be used in a research study approved by an NHS Research Ethics Committee.

6.7.2. Studies that are likely to involve the Organ Donation and Transplant (ODT) services of NHS Blood and Tissue (NHSBT), for example if retrieval involves Speciality Nurses in Organ Donation (SNODs), must be registered and approved by NHSBT.

6.7.3. It is permitted to use discarded samples that are generated as part of the process of preparing an organ for transplantation provided there is appropriate consent from a relative or legal representative.

6.7.4. Unless the facility is covered by a licence permitting removal, it is not permitted to take additional samples while removing an organ. There must always be appropriate consent to do this.

6.8. Advanced Therapies

6.8.1. There are separate regulations where cellular material derived from human tissue may be used for therapeutic purposes (the Human Tissue (Quality and Safety) Regulations 2007).

6.8.2. The procurement, testing, processing, distribution, import or export of cells, for therapeutic purposes, are all licensable activities regulated by the Human Tissue Authority.

6.8.3. A licensable activity may be carried out in an unlicensed facility provided there is a third party agreement between the licensed establishment and the other organisation. This particularly applies where tissue procurement is carried out in NHS hospitals for processing elsewhere.

6.8.4. A third party agreement is also required if an unlicensed establishment is providing goods or services that might affect the quality of the product.

6.8.5. The HTA must be given prior notification of the intended use of a third party establishment and the HTA has the authority to inspect any third party establishment.

6.8.6. There must be a documented system in place that ensures that every unit of tissue or cells can be identified at all stages from procurement through to end use (procurement, testing, processing, preservation, storage, transport, distribution or disposal, import and export).

6.8.7. The processed cells are usually regarded as Advanced Therapy Medicinal Products (ATMPs) so also come under the Clinical Trials Regulations (Statutory Instrument 2004:1031 Medicines for Human Use (Clinical Trials) Regulations 2004).

6.8.8. A consequence is that the processing establishment must hold a manufacturing licence with the Medicines and Healthcare Products Regulatory Agency (MHRA).

6.9. Non-consensual DNA analysis

6.9.1. It is a criminal offence to hold tissue samples with the intention of performing DNA analysis without consent unless:

(a) The material was collected before 2006 and it is not possible for the researcher to identify the person from whom the sample came; or

(b) The material comes from a living person and

(i) It is unlikely that the researcher would come into possession of information to identify the person from who the material came; and

(ii) It is for a specific research study that has been approved by an NHS Research Ethics Committee.

Standard 2 – HTA T1 (a), (b) & (c)
A coding and records system is in place to facilitate the traceability of bodies and human tissue, with a robust audit trail. ***Monitoring 3-8***

6.10. Traceability of Samples

6.10.1. A formal written record must be made by Theatre or laboratory staff for each and every tissue sample taken for research purposes. This is to make it possible to trace samples if there is ever a request from a tissue donor to know how the samples were used, and to enable auditing for compliance with the regulations.

6.10.2. For samples collected from Theatres, Pathology or Clinical Immunology, the record should include:

(a) Unique ID reference for the sample

(b) Location from where sample was collected (e.g. which surgical theatre)

(c) Patient's NHS number

(d) Trust's research study reference number (so-called RRK-number) or HBRC study reference number if the sample was collected for an HBRC approved study

(e) Identify of the person collecting the sample

(f) Date and Time of collection

(g) Confirmation that patient consent to donate the tissue was given

(h) Name and signature of the person collecting the sample

6.10.3. A copy of the record for samples collected from Theatres must be sent by theatre staff to Pathology which will maintain a central record store.

6.10.4. Other than licence staff, any person collecting the sample should be given only the unique id reference for the sample to ensure anonymity of the donors.

6.10.5. For samples collected directly by researchers for a specific research study then a log must be maintained on the Study Site File.

6.10.6. Researchers must keep a record of storage, use and disposal of samples.

6.10.7. This record must include:

(a) Tissue sample ID

(b) Trust's study reference number (RRK-number), or HBRC study reference number if the sample was collected for an HBRC approved study

(c) Exact location (institution, building, room, cupboard/fridge/freezer)

(d) Date sample stored

(e) Date sample used

(f) Date sample destroyed or if sent to a different organisation, the date the sample was sent and the contact details of the recipient

6.10.8. The samples themselves should be appropriately labelled with the sample id and study reference, but should not contain information that could directly identify the donor (such as name, NHS number or hospital number).

6.11. HBRC Retrieval Service

6.11.1. Staff employed by the HBRC are able to provide a service to retrieve tissue samples from surgical theatres or NHS diagnostic laboratories for specific research studies. These studies may be covered either by the Tissue Bank Ethical approval or by a study-specific ethical approval. When covered by study-specific ethical approval, samples should be retrieved anonymised.

6.11.2. This service is not appropriate if any additional procedures are required for the study (e.g. additional imaging or patient visits), or if non-routine clinical data is required, in which case the study should be submitted as a full application to an NHS Research Ethics Committee.

6.11.3. The HBRC applies a fee for use of the retrieval service.

6.12. HBRC Hosting Service

6.12.1. The HBRC provides a hosting service to store samples in HTA-compliant facilities for specific research studies.

6.12.2. These samples are stored for a specific study and access is controlled by the Chief Investigator of the study.

6.12.3. The samples do not come within the HTA research licence of the tissue bank or the Ethical approval for the bank.

6.12.4. At the end of the research study any residual samples must be destroyed, transferred into the HTA-compliant tissue bank's licensed collection or formally transferred into another specific study that has a Favourable Opinion from an NHS Research Ethics Committee.

6.12.5. The HBRC applies a fee for use of the hosting service.

6.13. Tissue collection from surgical theatres

6.13.1. If some tissue samples are required for diagnostic purposes and some for research, then the portion taken for research must not compromise the diagnostic utility of the remaining sample.

6.13.2. For this reason, a portion of a diagnostic sample may only be taken for research when approved by a pathologist or it is taken under the auspices of the HBRC.

6.13.3. The Trust's Pathology Laboratory will maintain a log of samples released for research. Samples may be retrieved for a specific study or by staff from the HBRC.

6.13.4. Samples can only be taken from Surgical Theatres if

(g) Prior notification of the request has been agreed with the lead surgeon; and

(h) A written record is completed detailing the removal of the tissue sample.

Standard 3 – HTA Code E (80-85)
All relevant material is held under a licence authorising the storage for use for a scheduled purpose. ***Monitoring 9-16***

6.14. Storage (licencing)

6.14.1. Subject to the exception below, Relevant Material collected for research purposes must be stored in premises that are licensed for research by the Human Tissue Authority

6.14.2. The exception is for Relevant Material collected for a specific research study approved by an NHS Research Ethics Committee which may be stored in any appropriate facility for the duration of the study.

6.14.3. There are no specific storage requirements for samples that are not considered Relevant Material, although material that requires processing to make acellular for non-specific research can only be stored for a maximum of 7 days outside a licensed facility.

6.14.4. Licensed facilities are subject to inspection by the Human Tissue Authority and must comply with quality standards issued by the HTA.

6.14.5. It is expected that unlicensed facilities holding samples for specific studies approved by an NHS Research Ethics Committee will follow some basic quality standards. These include:

(a) Temperature controlled (and preferably monitored) fridges and freezers

(b) Protection of samples from contamination

(c) Adequate labelling of samples

(d) Appropriate documentation

(e) Appropriate security measures

(f) Back-up procedures in case of emergency (e.g. power loss etc.)

6.14.6. Although samples collected for diagnostic purposes and stored in the Trust's pathology labs may be used for research, it is not possible to collect samples specifically for research and store them in the pathology labs, because they do not hold an appropriate HTA licence for research.

6.14.7. An unlicensed laboratory holding relevant material for diagnostic purposes may not advertise itself as a research resource, otherwise this would be deemed as a research collection and require licensing with the HTA.

6.15. Temporary Storage (pending processing or transport)

6.15.1. Samples containing cellular material that are intended to be processed to make acellular (and therefore not subject to licensing requirements), or that will be sent to another organisation, may be held for a short period in an unlicensed facility.

6.15.2. The HTA Code of Practice specifies this period as no more than 1 week. After that, the samples must be transferred to a licensed facility.

6.15.3. Similarly, samples that are intended to be transferred to a licensed tissue bank may be stored for no longer than a week in an unlicensed facility.

6.16. Licensed Tissue Banks

6.16.1. An important function of the Act was to establish a framework for promoting storage of collections of tissue samples for wider use in research.

6.16.2. The collections are held under research storage licenses issued by the Human Tissue Authority.

6.16.3. These collections are available to anyone wishing to use them for high quality research through a formal application process controlled by the Tissue Bank.

6.16.4. In Birmingham the main tissue bank is the Human Biomaterials Resource Centre (HBRC).

6.16.5. Applications to use samples are assessed by a scientific and ethical review committee. The samples cannot be held or reserved for specific researchers.

6.16.6. All samples must be released anonymised or link-anonymised (i.e. samples are labelled with a code so that although they are anonymised for the researcher, staff at the tissue bank retain the key to be able to re-identify the source of the samples for traceability purposes, or if further clinical information is required). Researchers must not make any attempt to try to identify the person from whom a sample is taken.

6.16.7. HBRC staff can retrieve and pass on associated clinical data from patient medical records linked to the samples.

6.16.8. An annual summary of researcher studies accessing samples held in the Tissue Bank must be submitted to the main ethics committee

Standard 4 – HTA Code E (86-93)
Any relevant material stored for a specific research project must have REC approval in place. Tissue banks may operate with generic ethical approval provided that the tissue bank is stored on an HTA-licensed premises.
Monitoring 17-19

6.17. Use (ethics)

6.17.1. Any research study that wishes to use Relevant Material for research (including material that will be processed to make acellular) must be approved by an NHS Research Ethics Committee.

6.17.2. The ethics review process will check the arrangements for consent, storage and use of samples.

6.17.3. Any change in the way samples will be collected, stored or used during the study must be notified to the ethics committee as an amendment.

6.17.4. Tissue samples collected for use for one research study may not be used for a different study unless the alternate study has received a favourable opinion from an NHS Research Ethics Committee and there is explicit consent from the donor for use of the samples in the new study or for generic research.

6.17.5. An HTA-licensed Tissue Bank may apply for a special form of review by an NHS Research Ethics Committee. Following a favourable opinion by the ethics committee, the Tissue Bank is given delegated authority to carry out ethical and scientific reviews on behalf of the main NHS Research Ethics Committee of studies proposing to use samples held by the bank: separate review by an NHS Research Ethics Committee is not required for these studies.

6.17.6. The Tissue Bank must provide an annual report to the main NHS Research Ethics Committee of all studies approved to access the facility (see section 6.12).

6.18. End of Study

6.18.1. At the end of a study the End of Study Procedures SOP should be followed.

6.18.2. If there are any samples remaining after the declaration of the end of a research study then they must either:

(a) Be destroyed

(b) Transferred back to the original NHS diagnostic laboratory if they remain of diagnostic value

(c) Transferred to an HTA Licensed Tissue Bank

(d) Formally transferred onto another research study that has a Favourable Opinion from an NHS Research Ethics Committee

6.18.3. Samples cannot be held pending a future application for favourable opinion from an NHS Research Ethics Committee

Standard 5 – HTA Code E (35-37)
Additional conditions must be adhered to when accessing relevant material from the deceased. ***Monitoring 20-21***

6.19. Deceased

Some additional specific rules apply to tissue samples taken from the deceased.

6.19.1. Appropriate consent from a relative or legal representative must be obtained to collect and use tissue samples from the deceased for the purpose of research, even if the samples are anonymised.

6.19.2. Removal of tissue sample from the deceased with the specific intention of using it for research can only be done in a facility that is licensed by the Human Tissue Authority (Post- Mortem licence)

6.19.3. In this Trust the Pathology Laboratory is the only facility licensed to remove tissue from the deceased: tissue intended for research cannot be removed from the deceased in the surgical theatres.

Standard 6 – HTA GQ1 (a)(d) & GQ2 (a)
All tissue handling arrangements are governed by documented policies and procedures covering all licensable activities. ***Monitoring 22-25***

7. Implementation and Monitoring

7.1.1. Review of tissue handling arrangements is included as part of the standard R&D Governance Office process for assessing research study applications.

7.1.2. The University of Birmingham Human Biomaterial Resource Centre has an extensive set of operating procedures

7.1.3. Standard procedures will be developed for tracking requests for tissue samples from surgical theatres and Trust pathology laboratories.

7.1.4. Researchers are required to complete and return annual progress reports to the R&D Governance Office. These reports are in a standard format and include questions about the collection, storage and use of tissue samples.

7.1.5. The R&D Governance Office has a schedule of random audits of research studies in the Trust. Part of the audit includes a review of the arrangements for handling tissue samples. A summary of audit findings is presented at each meeting of the R&D Management Group and annually to the Trust's Audit Committee.

7.1.6. The HBRC produces an Annual Report for the Healthcare Research Authority, which gives details of all studies approved by the HBRC. A copy is supplied to the Trust together with a breakdown of requests for samples from the Trust.

8. Duties

8.1. Head of Research and Development (R&D) Governance

8.1.1. Reviews the proposed collection, storage and use of human tissue samples in research studies

8.1.2. Oversees audits of active studies which includes assessment of collection and storage of human tissue samples

8.1.3. Provides assurance to the Board that the use of human tissue in research is carried out across the Trust under the HTA exemption for research approved by an NHS REC.

8.1.4. Approving all procedural documents associated with this policy and introducing and ensuring appropriate changes in practice where tissue is collected, stored and used for research under relevant exemptions.

8.2. Head of HBRC

8.2.1. Manages the process for collecting tissue samples for studies reviewed under the HBRC's NHS Research Ethics Committee favourable opinion.

8.2.2. Maintains a record of all tissue samples collected under the auspices of the HBRC

8.2.3. Provides an annual report to the NHS Research Ethics Committee, copied to the Trust, summarising collection and storage of tissue samples in the HBRC

8.3. Designated Individuals of HTA Licences

8.3.1. Ensures that tissue samples are only taken from pathology laboratories for studies that have been approved by the Trust's R&D Governance Office

8.3.2. Ensures that a record is kept of all requests for tissue samples. This record should be available for review by the Head of R&D Governance

8.4. Surgical Theatre Managers

8.4.1. Ensures that only tissue samples are only taken for research studies that have been approved by the Trust's R&D Governance Office, or by the HBRC review panel

8.4.2. Ensure that a record is kept of all tissue samples collected for research purposes and that a copy of the record is sent to the Head of Pathology services.

9. Associated Policy and Procedural Documents

9.1. SOP R&DSOP-04 End of Study Procedures

9.2. 1174 Data Protection, Confidentiality and Disclosure Policy

9.3. 024 Consent to Examination or Treatment Policy

10. References

10.1. Human Tissue Act 2004

10.2. Statutory Instrument 2007:1523 Human Tissue (Quality and Safety) Regulations 2007

10.3. Statutory Instrument 2004:1031 Medicines for Human Use (Clinical Trials) Regulations 2004

10.4. Human Tissue Authority Code E – Research (3rd April 2017)

10.5. Data Protection Act 2018

Appendix A

HTA Licences held by University Hospitals Birmingham and the University of Birmingham (November 2020)

Licence Type	Licensed Establishment	Designated Individual
Research	University of Birmingham School of Dentistry University of Birmingham Medical School (HBRC)	Phillip Tomson Christopher McCabe
Post-Mortem	Queen Elizabeth Hospital Birmingham Birmingham Children's Hospital Birmingham Women's Hospital	Rachel M Brown James Gray James Gray
Human Application	SWBH Birmingham and Midland Eye Centre (distribution, export and storage only) Queen Elizabeth Hospital Birmingham (distribution, procurement, storage and testing) University of Birmingham Medical School (procurement, processing, testing, storage)	Ankur Barua Shalini Chaudhri Philip Newsome
Organ Donation and Transplant	Queen Elizabeth Hospital Birmingham	Not required
Anatomy	University of Birmingham Medical School (storage)	Eric Jenkinson

Appendix B – Monitoring Matrix

	Monitoring Of Implementation	Monitoring Lead	Reported To	Monitoring Process	Monitoring Frequency
OVERARCHING ASSURANCE PROVISION					
An annual report to the Audit Committee provided by the Head of Research Governance will summarise the findings below and provide overarching assurance.					
STANDARD 1 - Consent					
1.	Appropriate consent to collect human tissue has been obtained prior to collecting, storing and using human tissue in research	HTA Licensees	Trust Board of Directors	Regulatory inspection, with feedback of report findings to Board	~5 yearly (research) ~2 yearly (human application) ~3 yearly (post-mortem) ~4 yearly (anatomy)
2.	Where exemption to consent is used to collect, store and use human tissue in research, that this is conducted in compliance with the Human Tissue Act	Head of R&D Governance	RIMG	Through RD&I's auditing of studies. Through relevant Datix reports.	According to audit schedule.
STANDARD 2 – Traceability					
3.	For all samples taken, for a research purpose, a formal written record is made.	Head of R&D Governance	RIMG	Through RD&I's auditing of studies. Through relevant Datix reports.	According to audit schedule.
4.	Integrity of the records taken must	Head of R&D	RIMG	Through RD&I's auditing of studies.	According to audit schedule.

	make it possible to trace samples to enable auditing for compliance with regulations	Governance		Through relevant Datix reports.	
5.	Samples collected from theatre, pathology or clinical immunology include all of the required information to ensure traceability	Head of R&D Governance	RIMG	Through RD&I's auditing of studies. Through relevant Datix reports.	According to audit schedule.
6.	A copy of all records for samples collected from theatre, pathology or clinical immunology must be held in a central store in pathology	Head of R&D Governance	RIMG	Through RD&I's auditing of studies. Through relevant Datix reports.	According to audit schedule.
7.	All researchers must keep a record of storage, use and disposal of samples.	Head of R&D Governance	RIMG	Through RD&I's auditing of studies. Through relevant Datix reports.	According to audit schedule.
8.	Samples collected by researchers are logged in the Study Site File	Head of R&D Governance	RIMG	Through RD&I's auditing of studies. Through relevant Datix reports.	According to audit schedule.
STANDARD 3 - Licensing					
9.	All relevant material collected for generic research purposes is stored on a premises with a licence from the HTA	Head of R&D Governance	RIMG	Through RD&I's auditing of studies. Through relevant Datix reports.	According to audit schedule.
10.	All relevant material collected for a specific research study approved	Head of R&D Governance	RIMG	List of studies involving Human Biomaterial. Through RD&I's auditing of studies.	Annually. According to audit

	by REC must be stored in an appropriate facility			Through relevant Datix reports.	schedule.
11.	Any material that requires processing to make acellular is only stored for a maximum 7 days outside a licensed facility	Head of R&D Governance	RIMG	Through RD&I's auditing of studies. Through relevant Datix reports.	According to audit schedule.
12.	Licensed facilities comply with the quality standards issued by the HTA	HTA - Licensees	Trust Board of Directors	Regulatory inspection, with feedback of report findings to Board	~5 yearly (research) ~2 yearly (human application) ~3 yearly (post-mortem) ~4 yearly (anatomy)
13.	Unlicensed facilities holding samples for REC approved research studies conform to appropriate quality standards.	Head of R&D Governance	RIMG	Through RD&I's auditing of studies. Through relevant Datix reports.	According to audit schedule.
14.	Any cellular samples being stored temporarily prior to being sent to another organisation may be held for a maximum 7 days.	Head of R&D Governance	RIMG	Through RD&I's auditing of studies. Through relevant Datix reports.	According to audit schedule.
15.	All samples held at a licensed tissue bank for research are held under a licence permitting research storage and released to researchers in non-identifiable	Head of R&D Governance	RIMG	Through RD&I's auditing of studies. Through relevant Datix reports.	According to audit schedule.

	formats.				
16.	All researcher studies accessing samples held in a tissue bank must be submitted to the REC and the Trust	Head of R&D Governance	RIMG	Through RD&I's auditing of studies. Through relevant Datix reports.	According to audit schedule.
STANDARD 4 – Ethical Approval					
17.	All research studies using relevant material for research are approved by REC	Head of R&D Governance	RIMG	Quality Control in trust procedures for assessing research study applications. RD&I Oversight of Quality Management System development and review.	Annually.
18.	Any changes to the way samples are collected, stored or used during a study must be notified to REC	Head of R&D Governance	RIMG	Quality Control in trust procedures for assessing research study amendment. Through RD&I's auditing of studies. RD&I Oversight of Quality Management System development and review.	Annually.
19.	Any samples remaining after the declaration of the end of study to the REC must be appropriately managed.	Head of R&D Governance	RIMG	Quality Control in trust procedures for assessing research study applications. List of closed studies involving human biomaterial. RD&I Oversight of Quality Management System development and review.	
STANDARD 5 – Accessing relevant material from the deceased					
20.	Consent is in place from the relative or legal representative of	HTA Licensees	Trust Board of	Regulatory inspection, with feedback of report findings to Board	~5 yearly (research) ~2 yearly (human

	the deceased prior to the tissue sample being collected and used for research purposes.		Directors		application) ~3 yearly (post-mortem) ~4 yearly (anatomy)
21.	Removal of tissue from the deceased is only performed at a facility with an appropriate licence.	Head of R&D Governance	RIMG	Quality Control in trust procedures for assessing research study applications. List of studies involving deceased donation. RD&I Oversight of Quality Management System development and review.	Annually.
STANDARD 6 – Implementation and monitoring					
22.	Reviews of tissue handling arrangements as part of the standard R&D governance office process for assessing research study applications.	Head of R&D Governance	RIMG	Quality Control in trust procedures for assessing research study applications. RD&I Oversight of Quality Management System development and review.	Annually.
23.	Operating procedures at each of the licensed facilities are regularly reviewed and changes implemented in a timely fashion	Head of R&D Governance	RIMG	RD&I Oversight of Quality Management System development and review. Through RD&I's auditing of studies. Through relevant Datix reports.	Annually.
24.	Standard tracking procedures are in place for tracking requests from surgical theatres and Trust pathology laboratories.	Head of R&D Governance	RIMG	RD&I Oversight of Quality Management System development and review. Through RD&I's auditing of studies. Through relevant Datix reports.	Annually. According to audit schedule
25.	Researchers complete annual	Head of R&D	RIMG	Receipt of annual report.	Annually

	reports in the standard format on the collection, storage and use of tissue samples.	Governance			