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1. PURPOSE AND SCOPE

1.1. The purpose of this Constitution is to set out the governance structure and other requirements of the Human Tissue Authority (HTA) Licence 12217 (‘the Licence’) held under the name of the Chancellor, Masters and Scholars of the University of Oxford (‘the University’). This is achieved by:

1.1.1. Providing general information on the background and composition of the Licence;
1.1.2. Setting out the structure, composition and reporting framework for the governance committees of the Licence;
1.1.3. Outlining the core documents under the Licence which further define compliance requirements of individual activities.

1.2. In accordance with Section 16(2)(e)(ii) of the Human Tissue Act 2004\textsuperscript{E1}, the University has several HTA research licences. This Constitution relates to the multi-site Licence number 12217\textsuperscript{E2} and is primarily for staff with governance responsibilities under the Licence.

1.3. Exclusions:

1.3.1. This Constitution does not apply to sample collections that are under the governance of other University licences (12168 Clinical Trials Service Unit, 12326 Oxford Centre for Diabetes, Endocrinology & Metabolism, 12433 Weatherall Institute of Molecular Medicine, 22496 Oxford DRWF Human Islet Isolation Facility, or 12178 Medical Sciences Teaching Centre).

1.3.2. This Constitution does not apply to sample collections held under a current and valid approval from a recognised Research Ethics Committee (REC). \textit{Note: University Research Ethics Committees and overseas Research Ethics Committees do not classify as recognised RECs for the purposes of the Act.}

2. DEFINITIONS

2.1. Unless otherwise stated, words or expressions contained in this Constitution shall bear the same meaning as in the Act\textsuperscript{E1}.

2.2. A table of key definitions can be found in Appendiex One.

3. INTRODUCTION

3.1. The University of Oxford is a world-renowned institution that undertakes ground-breaking research and innovation. The University’s work helps the lives of millions, solving real-world problems through a network of partnerships and collaborations. The breadth and interdisciplinary nature of the research undertaken sparks imaginative and inventive insights and solutions.

3.2. It is fundamental to the integrity of the research conducted at the University that all samples registered under the Licence have been acquired lawfully, with appropriate consent and are stored, handled, used and disposed of respectfully, sensitively, responsibly and in accordance with expressed wishes of the donor.

3.3. The activities and actions undertaken under the Licence will adhere to the four guiding principles of the HTA Codes of Practice\textsuperscript{E3}:

- Consent;
3.4. The Designated Individual (DI) for the Licence expects that all individuals working with human samples (from the living or deceased) stored under the Licence, strictly abide by procedures and standards set out by the HTA\textsuperscript{E3}, in this Constitution and other core documents for the Licence\textsuperscript{I1}.

3.5. The Licence has been in place since 2007 and was originally under the name of the Oxford Radcliffe Biobank but was subsequently changed to the John Radcliffe Hospital in 2015 to reflect the wider collections of samples stored under the Licence.

3.6. This Constitution should be read in conjunction with the HTA Licence Policy (HTA007)\textsuperscript{I2} and the other core documents for the Licence\textsuperscript{I1} (see section 9 for further information on the core documents for the Licence).

4. GOVERNANCE OF THE LICENCE

4.1. The governance of the Licence consists of both departmental and committee level responsibilities. These are outlined below and are illustrated in the organograms in Appendix Two.

4.2. Collection Responsible Officers
Collection Responsible Officers (CROs) assist PIs and PDs in the day-to-day governance and curation of samples. They are named staff members who serve as liaison between the DI/HTGT and the PDs/PIs and to whom responsibilities will be frequently delegated to perform actions related to HTA compliance and/or compliance with the terms of registration under the Licence. A list of the current CROs is contained within a local document held by HTGT (HTGT015\textsuperscript{I3}).

4.3. Corporate Licence Holder
The Corporate Licence Holder is the individual or corporate body responsible for holding the Licence. The role of the Corporate Licence Holder is not under any duty comparable to those of the DI; however, it is important to note that they have the right to apply to the HTA to vary the Licence. This enables them to substitute another person as the DI and allows the establishment to cover circumstances where the DI is unable to oversee the licensable activities. The Corporate Licence Holder of the Licence is the Chancellor, Masters and Scholars of the University. The Contact Person for the Corporate Licence Holder is Carolyn McKee.

4.4. Designated Individual
The Designated Individual (DI) is the person under whose supervision the licensed activity is authorised to be carried out. They have the primary (legal) responsibility under Section 18 of the Act\textsuperscript{E1} to secure: that suitable practices are used in undertaking the licensed activity; that other persons working under the Licence are suitable; and that the conditions of the Licence are complied with. The DI for the Licence is Dr Brian Shine.

4.5. Heads of Department, Departmental Administrators and/or delegated personnel
Heads of Department, Departmental Administrators and/or delegated personnel assist the DI in ensuring communications between the DI/HTGT and departmental staff are...
effective and appropriate. They are also a point of escalation for the HTGT in matters relating to licensing activity.

4.6. Human Tissue Governance Team for the Licence
The Human Tissue Governance Team (HTGT) for the Licence provide advice and support to the DI, PDs and staff working under the Licence to ensure that relevant material stored under the Licence adheres to the licensing requirements. HTGT communicate information to staff in departments and those working under the Licence through the governance and departmental structures.

4.7. Persons Designated
Persons Designated (PD) assist the DI in carrying out the legal duty of complying with the conditions of the Licence and the Act. There are PDs in each department that has a collection registered under the Licence. PDs direct others in relation to the Act and assist in developing and implementing procedures to provide the DI with assurance of compliance. PDs also support the CROs in the execution of their duties. In accordance with Section 17(b) of the Act, the names of the PDs will be provided to the HTA. A list of the current PDs is contained within a local document held by HTGT (HTGT015).

4.8. Principal Investigators and Chief Investigators
Principal Investigators (PIs) and Chief Investigators (CIs) storing human tissue samples are responsible for compliance with the Act, HTA Standards and Licence procedures and policy within their collection(s).

4.9. Main Committee structure
To oversee the requirements of the Licence there are two main committees which are intended to provide clear oversight, management and accountability for the licensed activities. These are the Human Tissue Governance Committee and the Risk Management Committee for Licence 12217. Both committees have reporting lines into the Medical Sciences Divisional Board (sometimes this could be directly or via the Finance, Research and General Purposes Committee (FRGPC)). The committee structure supports the DI in performing their role, but it does not relieve the DI of their ultimate responsibility and cannot therefore bind the DI to take specific actions. A committee structure for the Licence can be found in Appendix Two.

4.9.1. Human Tissue Governance Committee (HTGC) provides institutional direction and oversight of HTA licensing with respect to strategy, ethics, science and governance. It has representation from each of the University’s DIs, the Corporate Licence Holder, Clinical Trials and Research Governance (CTRG), Legal Services, and Oxford University Hospitals NHS Foundation Trust (OUHFT). An update on the activities of the Licence is provided to the Committee at each meeting.

4.9.2. Risk Management Committee of HTA Licence 12217 (RMC) is a Licence level committee that has responsibility for establishing a strategic approach to risk management for the Licence and ensuring that the approach is pro-active. The committee is also responsible for the overall co-ordination of risk management activity within its terms of reference. It supports the DI for the Licence in providing assurance against licensing requirements and is a mechanism to share learning and best practice. A copy of the terms of reference for this committee can be found on iPassport.
4.10. Other Committees and Meetings

To oversee the requirements of the Licence, and to support the main committee structure, there are various other committees, meetings and interactions that are intended to be mechanisms to disseminate information, escalate issues, discuss matters relating to the Licence and/or support staff in understanding the requirements of the Act and HTA standards:

4.10.1. Governance Management Committee for HTA Licence 12217 (formerly known as PD meetings) — are meetings that occur twice a year. It is attended by the PDs with responsibilities under the Licence as well as by Departmental Contacts. The meeting is a mechanism for the DI to update committee members on matters relating to the Licence and disseminate information. It is also an opportunity for members to escalate any issues and to share best practice. There is an agenda and the meeting is formally minuted. Agendas, minutes and any related papers for these meetings are stored in the ‘Meetings’ module on iPassport\[1\], which is accessible to all those with user accounts for the system.

4.10.2. HTA Forum — is an annual meeting organised by the HTGT and serves as a platform for knowledge sharing, discussion and information dissemination on matters relating to the Licence and research on human tissue samples more widely.

4.10.3. HTA Licence 12217 Drop-in Clinics – these are monthly informal opportunities for anyone in the University to come and speak with a member of the HTGT about all matters relating to the Act and the HTA standards. The dates for these clinics are published via email and on the HTGT website\[5\].

4.10.4. Human Tissue Governance Team meeting – is a regular meeting between the DI and the HTGT to discuss and report on matters relating to the governance of the Licence. Agendas are circulated for the meeting and an action log is kept, but it is not formally minuted.

4.10.5. Operational Management Committee for HTA Licence 12217 – are termly meetings for personnel (mainly CROs) operating under the Licence to promote communication, networking, discuss operational issues and the sharing of best practice between collections under the Licence. Agendas are circulated for the meeting and it is formally minuted. Agendas, minutes and any related papers for these meetings are stored in the ‘Meetings’ module on iPassport\[1\], which is accessible to all those with user accounts for the system.

4.10.6. Research Services Medical Sciences (MedSci) team meeting – is a fortnightly meeting attended by members of the HTGT and members of the Research Services MedSci team. The HTGT have a standing agenda item to provide an update on licence activity. Agendas are circulated for this meeting but it is not formally minuted.

4.10.7. Tricky Contracts meeting – this is a weekly meeting organised by the Research Contracts team to discuss and share issues relating to research contracts that are in the pipeline. At least one member of the HTGT attends the meeting to answer any queries relating to Licensing requirements and HTA Standards generally. There is no agenda for this meeting and it is not minuted.
5. **SCHEDULED PURPOSES**

5.1. Scheduled purposes are activities relating to the removal, storage and use of human tissue as listed in Schedule 1 of the Act that require consent.

5.2. The Licence allows storage of human samples for use for the Scheduled Purposes of: ‘research in connection with disorders, or the functioning, of the human body’; and ‘education or training relating to human health’.

5.3. More specifically, the Licence authorises the storage of relevant material which has come from a human body for use for the following Scheduled Purposes:

- **Part 1: Purposes requiring consent: General**
  - Determining the cause of death;
  - Establishing after a person's death the efficacy of any drug or other treatment administered to him;
  - Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including future person);
  - Public display;
  - Research in connection with disorders, or the functioning, of the human body;

- **Part 2: Purposes requiring consent: Deceased persons**
  - Clinical audit;
  - Education or training relating to human health;
  - Performance assessment;
  - Public health monitoring; and
  - Quality assurance.

5.4. The licensed activity should only be undertaken at the licensed premises stated in Section 6 in this document and under the supervision of the DI.

6. **LICENSED PREMISES**

6.1. Licensed premises are where the licensed activity (e.g. storage) takes place.

6.2. The establishment and maintenance of the Licence enables governance processes and oversight for the storage of relevant material in a registered collection for a Scheduled Purpose across various sites of the University and the OUHFT.

6.3. The licensed premises for the Licence are the John Radcliffe Hospital (main site) and four satellite sites: the Churchill Hospital and Old Road Campus; the Nuffield Orthopaedic Centre; the Department of Pharmacology building on Mansfield Road (in the University’s Medical Sciences Division); and the Peter Medawar Building on South Parks Road (in the University’s Medical Sciences Division).

6.4. The Licence previously included an additional satellite site (The Cowley Store), but this satellite site licence was revoked in February 2017 when all relevant material stored
under the Licence at this site was disposed of or transferred to other premises covered by the Licence.

6.5. The BioEscalator is not included as premises under the Licence.

7. INTERACTIONS WITH OTHER STAKEHOLDERS

7.1. Corporate Licence Holder
7.1.1. The Corporate Licence Holder is a member of the HTGC where matters relating to licensed activities of the Licence are discussed.
7.1.2. The Corporate Licence Holder contact may request information from the DI about licensed activities at any time.
7.1.3. The Corporate Licence Holder has the power to vary the Licence; as such, the DI must request any changes to the Licence (such as the addition or removal of satellite sites) via the Corporate Licence Holder contact.
7.1.4. The Corporate Licence Holder may substitute the DI to allow the University to cover circumstances where the DI is unable to oversee the licensable activities.

7.2. Human Tissue Authority
7.2.1. The DI is required to provide evidence of compliance to the HTA through the following mechanisms:
   - Self-compliance questionnaire completed biannually on the HTA portal.
   - Inspection by the HTA as and when requested by the HTA.
   - Weekly reports on new collections added to the Licence, any breach of licensing or consent requirements of the Act, any disposal of part or all of a sample collection.
7.2.2. The DI and/or HTGT may seek guidance from the HTA on any matters relating to licensed activities.
7.2.3. Inspection reports for the Licence are available publicly on the establishment page of the HTA’s website\textsuperscript{2}, a link to which is included on the HTGT’s website\textsuperscript{4} in the form of a clickable ‘widget’ button.
7.2.4. Any shortfalls against the HTA Standards for the Research\textsuperscript{3} sector and/or breaches of the Act identified by the HTA during an inspection of the Licence must be addressed by the DI through the implementation of a Corrective and Preventative Action plan (CAPA).

7.3. Medical Sciences Division
7.3.1. The Medical Sciences Division has representatives on the HTGC and the RMC for the Licence. Both of these Committees have in-direct reporting lines into the Medical Sciences Board.
7.3.2. The Medical Sciences Division also considers funding requests for certain operational aspects of the Licence.

7.4. Individual University Departments
7.4.1. PIs from nine Departments in the Medical Sciences Division store human tissue samples under the Licence:
7.4.2. Each Department storing tissue under the Licence has one or more PD(s) who assist the DI in overseeing licensed activities in the Department. See section 4.7 above for further information on the role of a PD.

7.4.3. Departments in the Medical Sciences Division not currently storing tissue under the Licence have one or more Departmental Contacts in place to ensure information is disseminated to staff who need it. For example, to ensure staff have received training on the requirements of the Act and HTA standards, or to ensure that samples are stored under the governance of the Licence when required.

7.4.4. Departmental staff communicate with the HTGT to ensure that relevant staff complete training on the requirements of the Act and HTA standards (WebLearn training\(^6\)).

7.4.5. Departmental staff may seek assistance and/or guidance, or raise concerns or queries on matters relating to human tissue governance by contacting the relevant PD in the first instance. Alternatively, they may contact the DI or the HTGT.

7.5. Oxford University Hospitals NHS Foundation Trust (OUHFT)

7.5.1. Many of the licensed premises covered by the Licence have shared occupancy between University of Oxford staff and OUHFT staff, particularly in the John Radcliffe Hospital, Churchill Hospital and Nuffield Orthopaedic Centre.

7.5.2. The University of Oxford and the OUHFT foster a strong research partnership through collaboration between the University's Research Services and the Trust's Research and Development Office. This is facilitated through the Joint Research Office.

7.5.3. The OUHFT and the University have entered into several research agreements pertaining to activities conducted under the Licence, particularly with regard to the operation of Research Tissue Banks.

7.6. Other Designated Individuals

7.6.1. The DI for the Licence interacts with the DIs of other University of Oxford HTA licences through participation in the HTGC:

- Research Licence 12168 – CTSU (Clinical Trial Service Unit and Epidemiological Studies Unit).
- Research Licence 12326 - OCDEM (Oxford Centre for Diabetes Endocrinology & Metabolism).
- Research Licence 12433 - Weatherall Institute of Molecular Medicine.
- Human Application Licence 22496 - Oxford DRWF Human Islet Isolation Facility.
- Anatomy Licence 12178 – University of Oxford, Medical Sciences Division, Medical Sciences Teaching Centre.

7.6.2. Other DIs for OUHFT licences are also invited to attend the HTGC:

- OUHFT Post-Mortem Licence 12052 – John Radcliffe Hospital.
- OUHFT Human Application Licence 11106 - Oxford Cell and Tissue Biobank (OCTB).

7.6.3. DIs cooperate through the sharing of learning, hosting shared events such as workshops, training events or attendance at the annual HTA Forum.

7.7. Other Research Services teams

7.7.1. Clinical Trials and Research Governance (CTRG):

7.7.1.1. The HTGT consults with the University’s Clinical Trials and Research Governance (CTRG) team on matters relating to ethical approval and governance for clinical trials and studies requiring review by a recognised Research Ethics Committee (REC).

7.7.1.2. The HTGT routinely directs enquiries from researchers regarding these matters to CTRG.

7.7.1.3. CTRG staff inform the HTGT whenever a study storing human tissue samples in Oxford submits an ‘end of study’ notification to the REC, so that any required procedures to register samples under the Licence may take place.

7.7.1.4. CTRG staff remind study staff of the ‘end of study’ arrangements detailed in their ethics applications for any leftover samples, to ensure appropriate governance is in place for any continued storage.

7.7.2. Research Contracts Specialists

7.7.2.1. The HTGT consults with Research Contracts Specialists in the Research Services team on matters relating to research agreements, such as Material Transfer Agreements (MTAs), Service Level Agreements (SLAs) and other contracts as required to ensure compliance with HTA Standards.

7.7.2.2. The HTGT provides advice to Research Contracts Specialists to ensure research contracts adequately address the requirements of the Act and HTA Standards.

7.7.2.3. Research Contracts Specialists alert the HTGT of any new projects where samples sourced from a third party are to be stored on licensed premises, to ensure appropriate governance arrangements are in place.

7.7.3. University Research Ethics Committees

7.7.3.1. The HTGT liaises with appropriate representatives of sub-committees of the Central University Research Ethics Committee (CUREC), specifically the Oxford Tropical Research Ethics Committee (OxTREC) and the Medical Sciences Interdivisional Research Ethics Committee (MS IDREC), to advise research staff on seeking the correct ethical review and approval for their projects.

7.7.3.2. OxTREC representatives alert the HTGT whenever approval is granted to a new project accruing samples on licensed premises, and facilitate contact between HTGT and researchers so that appropriate registration under the Licence may be undertaken when required.
7.7.3.3. MS IDREC representatives alert the HTGT to a project that intends to accrue samples on licensed premises at the time they receive an ethics application for review, and facilitate contact between HTGT and researchers so that appropriate registration under the Licence may be undertaken alongside the ethics approval process.

7.8. Principal Investigators (PIs) and Chief Investigators (CIs)

7.8.1. The HTGT assists PIs/CIs in achieving compliance through a process of registration, audits and sharing of learning.

7.8.2. The HTGT may contact PIs and CIs at any time to request information about their human tissue holdings stored on licensed premises.

7.8.3. PIs and CIs are required to provide any information requested about stored samples to assist with governance and oversight under the Licence. As part of these efforts, PIs and/or CIs may be requested to provide (whether they store samples registered under the Licence or not):

- Details of samples stored on licensed premises, including details of ethical approvals and agreements in place for the transfer of samples;
- Details of staff in their research groups undertaking work on human tissue samples and thus requiring training;
- Details on ‘end of study’ arrangements for ongoing or completed studies for which human tissue samples were collected in Oxford or transferred to Oxford.

7.8.4. PIs and CIs may request advice and guidance from the HTGT on matters related to licensed activities or human tissue governance, raise concerns about the Licence procedures or structure, or request meetings with HTGT or the DI at any time.

8. REGISTERED COLLECTIONS

8.1. The DI maintains oversight of samples stored under the governance of the Licence through a process of registration and audit of collections.

8.2. The process of registering a new collection under the Licence is outlined in the core Licence SOP ‘Registration’ (HTA011)\(^7\) and the process of auditing registered collections under the Licence is outlined in the core Licence SOP ‘Audit’ (HTA006)\(^8\).

8.3. Collections registered under the Licence are curated according to the consent (and ethical approval for Research Tissue Banks) under which the samples were obtained.

8.4. There are a number of legacy collections under the licence, that are archived and no longer being added to, but are available for use in research (subject to ethical approval of the study for which they wish to use them).

8.5. A number of samples are defined as ‘existing holdings’ (held prior to the Act coming into force on 1 September 2006), and are thereby exempt from the Act’s consent requirements.

8.6. Ethically approved Research Tissue Banks (RTBs) operating under the Licence

8.6.1. There are eight ethically approved RTBs which operate on licensed premises. These RTBs can release tissue and data anonymously for research under generic ethical approval granted to each RTB by a recognised REC. This means that researchers
receiving tissue from such biobanks do not need to apply for separate project-specific ethical approval, nor do they need to register separately to store the tissue under the Licence.

8.6.2. The eight ethically approved research tissue banks are:

- GI Illness Biobank.
- Oxford Brain Bank (OBB).
- Oxford Musculoskeletal Biobank (OMB).
- Oxford Radcliffe Biobank (ORB).
- Oxford Transplant Biobank (OTB).
- Oxford Vaccines Group Biobank (OVC).
- Pancreatic Cancer Research Fund Tissue Bank (PCRFTB Oxford)
- Quality in Organ Donation (QUOD).

8.6.3. See Appendix Two for related organogram.

9. CORE DOCUMENTS FOR THE LICENCE

9.1. There are a core set of documents held under the Licence which make up the Licence’s Quality Manual. They are stored on the quality management software system iPassport\(^{11}\) and are available for all persons working with collections registered under the Licence. The core documents for the Licence are as follows:

9.1.1. HTA001 Consent\(^{19}\): this SOP emphasises (amongst other things) the fundamental importance of adhering to the consent requirements of the samples held under the Licence.

9.1.2. HTA002 Traceability\(^{19}\): this SOP describes the requirements to document and maintain human tissue traceability from the point of collection or receipt to disposal, use to extinction or distribution of material stored under the Licence.

9.1.3. HTA003 Reporting and managing adverse events\(^{11}\): this SOP details the procedures in place to ensure that staff are open and honest about adverse incidents and events; that incidents are investigated promptly; robust actions are put in place and learning from such events occurs.

9.1.4. HTA005 Disposal\(^{12}\): this SOP describes the procedure for disposal of human samples and data stored under the Licence.

9.1.5. HTA006 Audit\(^{18}\): this SOP outlines the requirement for collections registered under the Licence to undergo rigorous and robust scrutiny against the requirements of the Licence, both upon registration, and throughout the time they are stored under the Licence. An annual audit schedule of the registered collections is in place with a focus on ensuring continual improvement as well as ensuring compliance with the licensing requirements.

9.1.6. HTA007 Policy on storage and use of human tissue samples under human tissue authority licence 12217\(^{2}\): this document sets out the rules governing the storage and use of tissue stored under the Licence.

9.1.7. HTA008 Human Tissue Authority Licence 12217 Constitution: this current document.

9.1.8. HTA009 Use of iPassport for Document Control and Records Management: this SOP provides staff with governance responsibilities under the Licence with details on the editor function of the iPassport quality management system.
9.1.9. **HTA010 Risk Management** and **HTA012 Risk Management Strategy for Human Tissue Licence 12217**

These documents outline the strategy and procedure for managing the risks at the Licence level.

9.1.10. **HTA011 Registration**

This SOP outlines the procedure to be followed for staff requesting registration of samples to be stored under the Licence.

9.1.11. **HTA013 iPassport procedures for users with view only access**

This SOP provides staff with view only access to iPassport with details about the system.

9.1.12. **HTA RA001 Core risk assessments for Licence 12217**

This document ensures that core risks related to the Licence are identified, collated, reviewed and managed appropriately.

9.2. **The core documents for the Licence are fundamental to ensuring that licensed activities are undertaken consistently, in accordance with regulatory requirements.**

9.3. **All staff working under the Licence are required to work according to the procedures set out in the core SOPs for the Licence.**

9.4. **iPassport is used as a mechanism to audit that those persons working under the Licence have read and acknowledged the core documents for the Licence that are relevant to them. This process is managed through the ‘skilled groups’ function of the system.**

10. **RESPONSIBILITIES OUTSIDE THE GOVERNANCE OF THE LICENCE**

10.1. **The DI and HTGT provide guidance on activities aligned within the scope of the Act**

and **HTA Standards**. Whilst the DI and HTGT may offer advice on matters outside the remit of the Licence, they have no authority to act in relation to these but will endeavour to provide signposts to other contacts where issues arise that are beyond the scope of the Licence. This includes matters relating to:

10.1.1. **The General Data Protection Regulation and the Data Protection Act 2018.**

10.1.2. Ethical applications and approvals for research studies.

10.1.3. Samples stored on non-licensed premises.

10.1.4. Samples of non-relevant material.

10.1.5. Activities of individuals not employed by the University of Oxford.

11. **FINANCE**

11.1. The funding to pay for the annual licence fee comes from the Research Services budget (which is accrued from the departments).

11.2. The funding to pay for the annual iPassport hosting service fees comes from the Medical Sciences Divisional Offices.

11.3. Research Tissue Banks or other registered collections under the Licence may implement cost recovery schemes to obtain reimbursement for some or all of their operational costs from researchers obtaining tissue samples from the biobank. Funds
recovered through cost recovery schemes are managed by each RTB independently of the Licence governance.

12. IPASSPORT SECURITY ARRANGEMENTS

12.1. iPassport is a hosted quality management system owned by Genial Compliance Systems Ltd (GCS). GCS is certified to ISO 9001:2015 and ISO 27001:2013 with scope covering design, development, support of iPassport and associated services.

12.2. The hosted iPassport system uses TLS AES 256bit encryption and uses port 443. TLS works by encrypting the data at the client side (web browser) using an authenticated security certificate and decrypting the data on the web/application server (iPassport). Therefore no plain text information is sent between the two points.

12.3. All data is stored within the European Union, based in Ireland.

12.4. Penetration testing is routinely conducted on iPassport against the OWSAP top ten guidelines.

12.5. GCS have backup and recovery strategies in place which includes a ‘point in time’ backup enabling system restore to any point in the previous month. Independent to this, a snapshot is taken on a monthly basis and this is retained on a rolling cycle for 12 months.

13. CONTACT DETAILS

13.1. For further information related to the contents of this document please contact the Human Tissue Governance Team (Licence 12217): hta_help@admin.ox.ac.uk

14. REFERENCES

14.1. Internal references

i1 iPassport for core documents/meetings module: https://htq.ipassportqms.com

i2 Policy on storage and use of human tissue samples under human tissue authority licence 12217: https://htq.ipassportqms.com/show_document?doc_id=1812ea7181b594abf5daaf92d9ca7209

i3 HTGT015 Contact List 12217: Available on the HTGT’S local shared drive G:\HTA_Governance_team\Licence governance\Contact list

i4 Terms of reference for the Risk Management Committee: https://htq.ipassportqms.com/show_document?doc_id=d48c0392210f0326e0081d1a99df45fa

i5 Human Tissue Governance University of Oxford website: https://researchsupport.admin.ox.ac.uk/governance/human-tissue

i6 Human Tissue Governance Training available on Weblearn via a link on HTGT website: https://researchsupport.admin.ox.ac.uk/governance/human-tissue/training
17 HTA011 Registration SOP:

18 HTA006 Audit SOP:
https://htg.ipassportqms.com/show_document?doc_id=2ab14cc3169aa1cd397602f1f65a012b

19 HTA001 Consent SOP:
https://htg.ipassportqms.com/show_document?doc_id=9a662e335e373c63fa45b69ee4eeef169

110 HTA002 Traceability SOP:
https://htg.ipassportqms.com/show_document?doc_id=f2f4f1863e6cc1f2d057e2a6da8672dd

111 HTA003 Reporting and managing adverse events SOP:
https://htg.ipassportqms.com/show_document?doc_id=f4e232da514cb55ce828fbf74a4e7174

112 HTA005 Disposal SOP:
https://htg.ipassportqms.com/show_document?doc_id=5c01ceb5963be2fb15057fbbddda0399

113 HTA010 Risk Management SOP:
https://htg.ipassportqms.com/show_document?doc_id=8dd9d46a671c8fca039f865637c8984e

114 HTA012 Risk Management Strategy for HTA Licence 12217:
https://htg.ipassportqms.com/show_document?doc_id=eccd0dca09c017429a8b29e7d4d9d6eb

115 HTA_RA001 Core Risk Assessments for HTA Licence 12217:
https://htg.ipassportqms.com/show_document?doc_id=bc5bb82324d4419ecc64b21b2b1b17e1

14.2. External references

E1 The Human Tissue Act 2004:
https://www.legislation.gov.uk/ukpga/2004/30/contents

E2 Human Tissue Act Licence 12217:
https://www.hta.gov.uk/establishments/john-radcliffe-hospital-12217

E3 Human Tissue Authority Standards and Codes of Practice for Research:
## 15. APPENDICES

### 15.1. Appendix One: Definitions

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biobank</td>
<td>A collection of biological material stored, together with the information attached to the material, for one or more purposes.</td>
</tr>
<tr>
<td>Constitution</td>
<td>Means this document and all the appendices to it.</td>
</tr>
<tr>
<td>Data Protection Act</td>
<td>An Act to make provision for the regulation of the processing of information relating to individuals, including the obtaining, holding, use or disclosure of such information.</td>
</tr>
<tr>
<td>Human samples</td>
<td>Are defined as any cellular or acellular human sample derived inside of the human body including but not limited to blood or blood derivatives (plasma, serum,uffy coat etc.), urine, faeces, saliva, tissue sections (stained or unstained), fresh frozen or fresh tissue samples, fixed samples (formalin, glutaraldehyde etc.) and formalin fixed paraffin embedded blocks.</td>
</tr>
<tr>
<td>Human Tissue Act 2004 (‘the Act’)</td>
<td>An Act of Parliament which details the legal (regulatory) framework for the collection, use, storage and disposal of human tissue in England, Wales and Northern Ireland. It also established the HTA to regulate activities concerning the removal, storage, use and disposal of human tissue.</td>
</tr>
<tr>
<td>Human Tissue Authority (‘the HTA’)</td>
<td>Is the independent regulator established in 2005 and regulates organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, education and training, and display in public. They achieve this task by defining standards, issuing licences for ‘scheduled purposes’ and inspecting licensed premises or institutions.</td>
</tr>
<tr>
<td>Human Tissue Authority Licence 12217 (‘the Licence’)</td>
<td>Is a research licence issued by the HTA that allows the University to store relevant material on licensed premises.</td>
</tr>
<tr>
<td>Material Transfer Agreement (MTA)</td>
<td>Material transfer agreements set out the conditions under which a transfer of scientific material is made from one party to another for the purposes academic research.</td>
</tr>
<tr>
<td>Research Ethics Committees</td>
<td>Research Ethics Committees safeguard the rights, safety, dignity and well-being of research participants by providing ethical review of research studies and clinical trials.</td>
</tr>
</tbody>
</table>
| Recognised Research Ethics Committees | A recognised REC for the purposes of the Act is either:   
|                                          | a) A REC recognised or established by, or on behalf of, the HRA under the Care Act 2014 or any other group of persons which assesses the ethics of research involving individuals and which is recognised for that purpose by, or on behalf of, the Welsh Ministers or the Department of Health in Northern Ireland; or  
|                                          | b) An ethics committee recognised by United Kingdom Ethics Committee Authority to review clinical trials or investigational medicinal products under the Medicines for Human Use (Clinical Trials) Regulations 2004. |
| Relevant material         | Is defined in Section 53 of the Act to mean ‘Material, other than gametes, which consists of or includes human cells’. References to relevant material from a human body do not include embryos outside the human body, or hair and nail from the body of a living person. |
| Research Tissue Bank (RTB) | A collection of human tissue or other biological material which is stored for potential research use beyond the life of a specific project with ethical approval or for which ethical approval is pending. |
| Scheduled Purposes        | The Act sets out a list of purposes requiring consent, for which material might be removed, used or stored. Collectively, these purposes are referred to as ‘Scheduled Purposes’. |
| The University            | Means the University of Oxford, whose full title is ‘The Chancellor Masters and Scholars of the University of Oxford’. |
| Working with human samples | Is defined as being involved with seeking consent for the collection of human tissue samples, collecting, processing, storing, using, releasing or disposing of human tissue samples, as well as any staff involved in managing ethics approvals for projects involving human samples or writing documents relating to human tissue samples. |
15.2. Appendix Two: Organograms
15.2.1. The Licence structure

[Diagram of organogram]

Key:
- = Research
- = Tissue Bank

Author(s): Rachel Lloyd
15.2.2. The Governance Structure

Designated Individual (DI)
(Brian Shine)

Human Tissue Governance Team
(Rachel Lloyd, Marie Hamard,
Gretchen Meddaugh, Ben Haxton)

Persons Designated (PDs)

Principal Investigators (PIs)

Collections Responsible Officers (CROs)

All staff working under the licence

Corporate Licence Holder contact
(Carolyn McKee)

Departmental contacts for
departments not holding
material under 12217

15.2.3. The Committee Structure

Medical Sciences Board

MSD Finance, Research and General Purposes Committee

Human Tissue Governance Committee

Risk Management Committee for Licence 12217