Title:	**Quality Manual**		
Reference Number:	QUB-HTA MANUAL-001	Date prepared:	18 June 2013
Version Number:	v 10.0	Revision Date:	12 September 2025
Effective Date:	08 July 2013	Review Date:	September 2028

	Name and Position	Signature	Date
Author:	Dr Paula Tighe Research Governance Manager	----------	
Reviewed by:	Human Tissue Steering Group	----------	
Approved by:	Professor Christopher Scott, Chair Human Tissue Steering Group	----------	

This is a controlled document.
When using this document please ensure that the version is the most up to date by checking the Research Governance Website

Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
1.0	12/08/2013	NIB and Anatomy SOPs lists amended	2.0
2.0	14/01/2014	Change to PDs & HTSG membership updated. Centre for Vision and Vascular Science changed to Centre for Experimental Medicine. References to HTA eLearning removed.	3.0
3.0	06/10/2014	Change to PDs and HTSG membership. HTSG membership moved to appendix Reference to Code of Conduct and Integrity in Research included. Research Governance and Integrity Committee name updated.	4.0
4.0	24/04/2017	Review in response to Human Tissue Authority's Codes of Practice and Standards update.	5.0
5.0	9 April 2019	Bi-Annual review which resulted in amendments to the titles of the University's Research Ethics Policy, the Regulations Governing an Allegation of Misconduct in Research, the new Pro-Vice Chancellor for Research and Enterprise and capturing Precision Medicine Centre.	6.0

6.0	4 November 2021	Bi-Annual review which resulted in amendments to: Reflect Academic progression for J James, L McGarvey, B Green; Add S Cameron as PD for Biological Sciences Remove E Murray and A Al-Modhefer as PDs for Anatomy; Reflect changes in University Structure; Reflect new naming format for Research Governance SOPs	7.0
7.0	4 November 2022	Section 11 – Contact Information reviewed and corrected. Figure 1 revised to reflect new PDs in Anatomy and to add Dr Donna Small as PD for MBC/BCH Licence. Hyperlinks verified and updated where appropriate.	8.0
8.0	22 February 2024	Updated to include commercial companies operating under the University's HTA Licence, change of HTSG Chair and addition of PDs.	9.0
9.0	12 September 2025	Addition of new Anatomy PDs.	10.0

Contents

1. Background

The Human Tissue Act 2004 (HT Act) came into force on 1 September 2006 and provides a framework for regulation of research involving the removal, storage, use and disposal of human tissue defined as relevant material (ie) material that has come from a human body and consists of, or includes, human cells.

The definition of relevant material and a supplementary list of materials can be found on the Human Tissue Authority's website:
https://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004
The Human Tissue Authority (HTA) is the regulatory body which licences establishments storing and using relevant material for 'scheduled purposes' such as research in connection with disorders, or the functioning, of the human body or anatomical examination. The HTA have issued Codes of Practice which detail the standards expected from licenced establishments. These Codes of Practice include:

(i) Code A: Guiding Principles and the fundamental principle of consent
(ii) Code B: Post-mortem examination and Standards
(iii) Code C: Anatomical examination and Standards
(iv) Code D: Public display and Standards
(v) Code E: Research and Standards
(vi) Code F: Donation of solid organs and tissue for transplantation
(vii) Code G: Donation of Allogenic bone marrow and peripheral blood stem cells for transplantation

Codes of practice can be accessed from the HTA website:
https://www.hta.gov.uk/codes

Informed consent is the fundamental principle behind the HT Act and must be in place for the removal, storage and use of relevant material for 'scheduled purposes'. Details of 'scheduled purposes' and the differing consent requirements from the living and the deceased can be found here: http://www.legislation.gov.uk/ukpga/2004/30/schedule/1.

In order to ensure compliance with licensing requirements the University has developed regulations, policies and Standard Operating Procedures (SOPs). An overview of these and the management of HT Act related activities are provided in this Quality Manual.

2. Regulations and Policies

The University has established regulations and policies to govern research and maintain the integrity of research carried out under its auspices. The University's HT Act related regulations and policies are:

2.1 Regulations for Research Involving Human Participants

All research involving human participants, their tissue or data, falls within the remit of the Regulations for Research Involving Human Participants. These Regulations provide direction for researchers and detail the processes and procedures required to ensure that:

(i) all staff are aware of their responsibilities and the need for appropriate training, eg training on the HT Act 2004, compliance with the University's Policy on the

Ethical Approval of Research, training in consent or Good Clinical Practice (GCP) when the HSC sector is involved;
(ii) the planned research is of a high scientific quality;
(iii) the researcher has identified and secured the necessary resources to complete the research;
(iv) all necessary regulatory and ethical approvals are in place;
(v) appropriate indemnity provision is in place;
(vi) appropriate monitoring and reporting will take place.

2.2 Policy on the Ethical Approval of Research

The Policy on the Ethical Approval of Research addresses the issues involved in the ethical approval and conduct in research, in particular that involving human participants their tissue or data, animals and the environment. It provides general guidance on the standards expected and the requirements for the ethical approval of research.

2.3 Regulations Governing the Allegation and Investigation of Research Misconduct

The Regulations Governing the Allegation and Investigation of Research Misconduct detail the processes to be followed when an allegation of research misconduct is received.

Within the Anatomy area there is also an Anatomy Code of Conduct which details the standards expected and local policies are in place to govern activities.

2.4 Code of Conduct and Integrity in Research

The Code of Conduct and Integrity in Research addresses the issues involved in the proper conduct of research and provides guidance for staff and students on the standards expected when undertaking research within or on behalf of the University.

3. Responsibilities

3.1 Licence Holder

The University is the Licence Holder for the MBC/BCH, RVH and Anatomy Licences. The Licence Holder's representative is the Dean of Innovation and Impact, Faculty of Medicine, Health and Life Sciences. The Licence Holder can make applications to the HTA to vary a licence, including change of Designated Individual (DI). The Licence Holder's representative, or their nominee, fulfils the role of Chair at the Human Tissue Steering Group (HTSG).

3.2 Designated Individual

The DI is ultimately responsible for the implementation of the requirements of the HT Act for their licenced areas. The DI is the person under whose supervision the licenced activity is authorised to be undertaken. The DI has primary (legal) responsibly under section 18 of the HT Act to secure:

(i) That suitable practices are used in undertaking the licensed activity;
(ii) That other persons working under the licence are suitable and;
(iii) That the conditions of the licence are complied with.

The University has three DIs - Professor Jackie James for the MBC/BCH Research licence (12044), Dr Gareth McKay for the RVH Research Licence (12059) and Dr Samantha Taylor for the Anatomy Licence (12113).

3.3 Persons Designated

PDs are individuals nominated by the DI, and when nominated in a notice to the HTA, are considered to be a person to whom the licence applies (ie a person to whom the authority conferred by the licence extends). PDs support the DI and provide direction and guidance for others in relation to HT Act related actives at a School/Centre level. In addition, for those Commercial Companies operating under the University's HTA Licence a PD at company level is appointed to provide guidance at company level and help ensure compliance. All PDs must sign a consent form indicating their agreement to undertake the role and the associated responsibilities.

PD responsibilities include:

(i) Ensuring that all those involved in human tissue related activities are aware of QUB HTA policies and procedures, including consent, tracking, storage, use, transfer and disposal, and the requirement to comply with them;
(ii) Providing advice on the regulations and requirements for all human tissue related research activity within area of responsibility;
(iii) Awareness of all those working with human tissue within their area of responsibility and pass on changes in groups/individuals doing research using human tissue to enable regular updating of database;
(iv) Facilitating the monitoring of compliance with the HT Act, QUB HTA policies and procedures;
(v) Attendance at Human Tissue Compliance meetings and HTSG to provide knowledge of facilities and working practices within area of responsibility and to ensure relevant information is fed back as required.

3.4 Research Governance

The Research Governance Team are responsible for control and maintenance of the University policies and procedures, including the Regulations Relating to Research Involving Human Participants, the Policy on the Ethical Approval of Research, and the University's SOPs relating to the HT Act. Other responsibilities include scoping and dissemination of new or revised legislation and good practice, compilation and execution of the annual audit programme, delivery and organisation of HT Act related training, administration of HTSG, maintenance of records and related documentation (master copies of SOPs and MTAs), provision of access to the Human Tissue Register and investigation of allegations of research misconduct, including non-compliance with the HT Act.

3.5 University Staff and students

Staff and students who undertake HT Act related activities are responsible for ensuring that all activities are conducted in compliance with the University's regulations and SOPs. These responsibilities include:

(i) Ensuring that there is appropriate informed consent for the removal, storage and use of the material and that consent was obtained in accordance with the Human Tissue Authority code of practice on Consent;
(ii) Ensuring that all relevant approvals for the research are in place;

(iii) Attendance at relevant training, including HT Act training and informed consent training as appropriate;
(iv) Adherence to University policies and procedures including the University's Regulations for Research Involving Human Participants, the Policy on the Ethical Approval of Research and the Code of Conduct and Integrity in Research;
(v) Making available for audit all sample collections and records relating to material falling within the HT Act;
(vi) Complying with the HTA Codes of Practice;
(vii) Appropriately labelling, logging and tracking specimens with details of consent, use and/or storage location in accordance with the relevant SOPs;
(viii) Transferring relevant material to non-QUB licensed premises under the terms of an appropriate agreement;
(ix) Maintaining records of imported relevant material;
(x) Compliance with and documentation of, any specific disposal arrangements that have been requested by consenting donors;
(xi) Disposing of relevant material appropriately;
(xii) Storing human tissue (as defined by the HT Act) in suitable secure conditions;
(xiii) Reporting adverse events promptly to the DI, PD and as appropriate the CI, in accordance with the University procedures.

Details of PDs for each area are provided in figure 1 and in the Contacts section of this manual.

3.6 Commercial Companies and their Staff

Commercial companies that operate under the University's HTA Licence. These companies and their staff are responsible for ensuring that all activities are conducted in compliance with the University's SOPs for Human Tissue. Given their status as separate legal entities, contractual arrangements, eg Facilities Agreement, will also outline the requirements that must be adhered to ensure the University's Human Tissue licence is not compromised. This will include, but is not limited to, the companies' obligations with regard adhering to the University HTA procedures and the University's right to audit and test compliance.

The responsibilities of commercial companies and their staff include:

(xiv) Ensuring that there is appropriate informed consent for the removal, storage and use of the material and that consent was obtained in accordance with the Human Tissue Authority code of practice on Consent;
(xv) Ensuring that all relevant approvals for the research are in place;
(xvi) Attendance at relevant training, including HT Act training and informed consent training as appropriate;
(xvii) Adherence to relevant University policies and procedures in relation to the Human Tissue Act;
(xviii) Making available for audit all sample collections and records relating to material falling within the HT Act;
(xix) Complying with the HTA Codes of Practice;
(xx) Appropriately labelling, logging and tracking specimens with details of consent, use and/or storage location in accordance with the relevant SOPs;
(xxi) Transferring relevant material to non-QUB licensed premises under the terms of an appropriate agreement;
(xxii) Maintaining records of imported relevant material;

(xxiii) Compliance with and documentation of, any specific disposal arrangements that have been requested by consenting donors;
(xxiv) Disposing of relevant material appropriately;
(xxv) Storing human tissue (as defined by the HT Act) in suitable secure conditions;
(xxvi) Reporting adverse events promptly to the DI, PD and as appropriate the CI, in accordance with the University procedures.

Although the companies are required to adhere to the relevant QUB HTA SOPs (section 6.3), the following remain under the remit and responsibility of the company:

i) Data Protection Policy, Privacy Notice(s) and establishment of data/record retention schedules;
ii) Securing a favourable Research Ethics Committee opinion for research studies;
iii) Human Resources related polices such as Personal Development Review processes;
iv) Processes for dealing with misconduct in research.

4. Licences and Organisation Structure

The University holds two research licences and one anatomy licence. The licences cover the following areas:

(i) MBC/BCH Research Licence 12044 (DI Professor Jackie James)
- Patrick G Johnston Centre for Cancer Research (PGJCCR)
- Wellcome_Wolfson Institute for Experimental Medicine (WWIEM)
- School of Pharmacy
- School of Psychology
- School of Biological Sciences

(ii) RVH Research Licence 12059 (DI Dr Gareth McKay)
- Centre for Public Health

(iii) Anatomy Licence 12113 (DI Dr Samantha Taylor)
- Anatomy licenced area, Centre for Biomedical Sciences Education

Figure 1 provides an overview of the licencing structure.

5. University Committee Structure

The reporting structure for University Committees is provided in Figure 2 - Overview of University Committee Structure. The roles of the relevant committees are summarised below.

5.1 Senate

The governing body of the University is Senate which is responsible for the on-going strategic direction of the University, the management and administration of its revenue and property and the general conduct of its affairs.

5.2 Academic Council

The primary academic body of the University is Academic Council, which is responsible for the control of internal academic affairs and arrangements for teaching and research.

5.3 Research and Innovation Committee

The Research and Innovation Committee is responsible for promoting and encouraging high quality research in the University. The Committee advises Academic Council on the development and implementation of the University's research strategy. Research Governance Ethics and Integrity Committee (RGEIC) reports to Research and Innovation Committee.

5.4 Health and Safety Management Group

The Health and Safety Management Group is responsible for making recommendations to the University on policy and strategy relating to management of health and safety.

5.5 Risk Management Committee

The purpose of this Committee is to oversee risk management arrangements within the University, ensuring that programmes and procedures are undertaken in such a manner as to minimise the exposure of the University to unacceptable levels of risk

5.6 Biological and Infectious Agents Advisory Committee

This Committee provides specialist advice and guidance on the use of genetically modified organisms and infectious agents at work. It make recommendations to the Health and Safety Management Group on policy and arrangements required under current or proposed biological Health and Safety regulations, Approved Codes of Practice and Guidance.

5.7 Research Governance, Ethics and Integrity Committee

The RGEIC is responsible for ensuring that the University complies with the requirements of the UK Policy Framework for Health and Social Care Research (2018), the Medicines for Human Use (Clinical Trials) Regulations 2004 and the Human Tissue Act 2004 and other associated legislation/guidelines. It is also responsible for developing, implementing and updating the University policies and procedures relating to the ethical approval of research and ensuring that these are reflective of the national regulatory framework. The HTSG reports to RGEIC.

5.8 Human Tissue Steering Group

The HTSG is responsible for the implementation of the requirements of the HT Act at QUB. It has a duty to provide guidance to University staff to ensure compliance with the Act, HTA Codes of Practice and applicable Directives and Legislation governing the procurement, transfer, use, storage or disposal of human tissue. The HTSG is chaired by the Licence Holder's named representative, or their nominee, and consists of DIs, PDs and members of the Research Governance Team. HTSG membership is detailed in Appendix 1.
Terms of Reference:

The HTSG is tasked with:

(i) the co-ordination and implementation of the requirements of the HT Act at QUB
(ii) the development and implementation of policies, systems and procedures to ensure QUB conducts its business in accordance with the HT Act and HTA Codes of Practice
(iii) responding to, analysis, development and making necessary changes to QUB policy, systems and procedures, further to new and/or amended legislation that impact on the implementation of the requirements of HT Act at QUB
(iv) ensuring that staff (including holders of honorary contracts) are appropriately trained to work in accordance with the provisions of the HT Act and that any update training is provided as and when required
(v) providing guidance on operating procedures and any related risks to ensure compliance with the HT Act
(vi) the dissemination of relevant HT Act information to staff
(vii) liaising with NHS Trust partners to enhance collaboration and the sharing of procedures
(viii) supporting the DIs and PDs in the execution of their duties
(ix) providing council to the RGEIC in relation to any developments and recommending implementation measures to ensure that the University is compliant with the HT Act
(x) drafting any policies and regulations to be considered by the RGIC and providing regular reports to the RGEIC

5.9 Commercial Company Human Tissue Sub-Group

The Commercial Company Human Tissue Sub-Committee is responsible for the reviewing HTA related policies and procedures which may impact on the ability of the companies to operate under QUB's HTA Licences and raising issues which may impact on the University's compliance with the Human Tissue Act. The Commercial Company Human Tissue Sub-Committee is chaired by the DI, or their nominee, and consists of PDs from the Commercial Companies, representation from QUBIS and members of the Research Governance Team. The Commercial Company Human Tissue Sub-Committee reports to Human Tissue Steering Group.

6. Standard Operating Procedures

The University has developed SOPs which detail the procedures that must be followed for HT Act related activities. The SOPs should be read in conjunction with the relevant HTA Code of Practice.

The Precision Medicine Centre (PMC) is a collaborative arrangement between the Belfast Health and Social Care Trust (BHSCT) and the University. The laboratory operates two core interconnected sections Genomics and Tissue Hybridization and Digital Pathology The PMC works in partnership with the Northern Ireland Biobank (NIB) and both the PMC and NIB have their own suite of SOPs.

6.1 Research SOPs

For the MBC/BCH and RVH research licences (excluding the PMC and NIB) the following SOPs apply:

(i) Informed Consent for Research (QUB-RGEI-004)
(ii) Receipt, Labelling, Tracking and Storage of Human Tissue (QUB-HTA-001)
(iii) Disposal of Human Tissue (QUB-HTA-002)

(iv) Internal Audit of Human Tissue Authority Licenced Premises, Facilities and Equipment (QUB-HTA-003)
(v) Recording HTA Related Adverse Events (QUB-HTA-004)
(vi) Assessment of Risk to Personnel for the Handling of Human Tissue (QUB-HTA-005)
(vii) Assessment of Risk to Human Tissue (QUB-HTA-006)
(viii) Transfer and Export of Relevant Material (QUB-HTA-007)
(ix) Import of Relevant Material (QUB-HTA-008)
(x) Transportation of Human Tissue (QUB-HTA-009)
(xi) Withdrawal of Consent – Human Tissue (QUB-HTA-010)
(xii) Complaints from Research Participants (QUB-RGEI-019)
(xiii) Research Governance Audit (QUB-RGEI-015)

The most up to date version of the above SOPs can be found on the University's Research Governance website:

http://www.qub.ac.uk/Research/Governance-ethics-and-integrity/Human-tissue/

These SOPs are considered to be controlled documents and staff and students must check the Research Governance website to ensure they are using the most up to date versions. Master copies of the University's Research SOPs are maintained within the Research Governance Office. SOPs are reviewed by the HTSG every two years or more frequently if required due to changes in legislation or practice.

Other research related SOPs are also available on the Research Governance website for reference.

Local SOPs have been developed for certain areas where required. Local SOPs are based on the principles outlined in the University SOPs but have been detailed to suit local practices.

6.2 NIB and PMC SOPs

The most up to date version of the NIB SOPs can be found on the NIB SharePoint site. The SOPs are controlled documents. Master copies of these NIB SOPs are held by the NIB administrator and are reviewed by the senior staff of the NIB every two years. SOPs relating to the Precision Medicine Centre are accessed via the PMC.

6.3 Commercial Company SOPs

Commercial companies are required to adhere to the following QUB HTA SOPs:

i) Receipt, Labelling, Tracking and Storage of Human Tissue (QUB-HTA-001)
ii) Disposal of Human Tissue (QUB-HTA-002)
iii) Internal Audit of Human Tissue Authority Licenced Premises, Facilities and Equipment (QUB-HTA-003)
iv) Recording HTA Related Adverse Events (QUB-HTA-004)
v) Assessment of Risk to Personnel for the Handling of Human Tissue (QUB-HTA-005)
vi) Assessment of Risk to Human Tissue (QUB-HTA-006)
vii) Transfer and Export of Relevant Material (QUB-HTA-007)
viii) Import of Relevant Material (QUB-HTA-008)
ix) Transportation of Human Tissue (QUB-HTA-009)
x) Withdrawal of Consent – Human Tissue (QUB-HTA-010)

xi) Research Governance Audit (QUB-RGEI-015)

In addition, commercial companies are required to develop and maintain their own SOPs to cover activities in the following areas, which must include the minimum information as outlined below, and be subject to appropriate document control and periodic review:

i) Informed Consent for Research
- The processes required for obtaining consent from research participants in accordance with the Human Tissue Act, including guidance on the written information to be provided to participants
- Availability of language translations and formats suitable for the participant population
- That consent forms demonstrating enduring and generic consent are retained for the same duration as the samples stored under the HTA licence
- The processes to ensure agreements cover consent in accordance with the requirements of the HT Act and the HTA's Codes of Practice, where consent is obtained by third parties

ii) Education, Training and Experience
- Those working with human tissue must attend QUB Human Tissue Act training and this training must be renewed every 3 years
- Those involved in obtaining informed consent must be appropriately trained
- Qualifications of staff and training records are retained
- Competency assessed and maintained

iii) Complaints from Research Participants
- Where the complaint/matter relates to human tissue or an activity undertaken under the auspices of the University's Human Tissue Licence, the DI must be informed

iv) Data Management and Maintaining Records
- Requirements in relation to maintaining of records, both hardcopy and electronic associated with the collection and use of HTA relevant material
- For imported relevant material, records must be retained for 5 years after disposal of the material

Commercial company SOPs will be subject to audit as part of the Research Governance Audit programme to ensure compliance with the HTA Codes of Practice and Standards. Commercial company SOPs may also be subject to review and scrutiny by Human Tissue Steering Group on request.

6.2 Anatomy SOPs

Authorised copies of Anatomy SOPs are found in the following areas –

(i) Anatomy General Office;
(ii) Mortuary – Room 0B/300, Medical Biology Centre;
(iii) Dissecting Room preparation area – Room 01/314, Medical Biology Centre;
(iv) Research Governance – 63 University Road.

Master copies of the University's Anatomy SOPs are maintained by the Anatomy DI.

7. Audit

7.1 Research Studies

Audits of research studies outside the PMC and NIB are undertaken regularly to provide assurance to the University on compliance with the HT Act requirements and assist researchers in meeting the expected standards. Various approaches are taken to examine HTA compliance from different perspectives. This includes the interrogation of the Queen's Online (QOL) Tissue Register as the source data to select at random 10% of each area's studies for audit, or the review of compliance with Material Transfer Agreements. The methodology and annual audit plan is reviewed and ratified by the HTSG. The audit programme will include projects/studies involving the use of human tissue that are undertaken by commercial companies are operating under the University's HTA Research Licences. In addition, the Research Governance Team and/or Director of Research and Enterprise reserve the right to undertake a targeted audit, if they have suspicion of non-compliance to legislation, or when monitoring reports provide information of concern. Audits will be conducted in accordance with the SOP Research Governance Audit (QUB-RGEI-015).

In addition, the PMC and the NIB implement their own audit programme which includes the NHS Molecular Diagnostic Service.

7.2 Anatomy

An audit of the Anatomy licenced area is undertaken on an annual basis. A random sample of records, donors and retained specimens are audited to ensure the required documentation is available, accurately completed and that donors and specimens are appropriately tagged to ensure traceability.

7.3 Research and Anatomy Licenced Premises

The internal audit of premises is undertaken to provide assurances to the University that the premises, facilities and related equipment are fit for purpose and comply with the licensing standards required by the HTA. All HTA licenced premises will be audited every three years or more frequently if requested by a DI or PD. The Research Governance Team accompanied by the area PD and/or the DI conduct the internal audit of HTA licenced premises, facilities and related equipment. A PD from another area will be invited to take part on the audit process to enhance shared learning. For areas in which commercial companies are operating the audit personnel will be limited to members of the Research Governance Team and/or DI. Audits will be conducted in accordance with the HTA SOP Internal Audit of Human Tissue Authority Licensed Premises, Facilities and Equipment (QUB-HTA-003).

8. Training

The University expects that all individuals involved in HT Act related activities will be appropriately trained.

8.1 Designated Individuals

All DIs must be appropriately experienced and qualified for the role.

8.2 Persons Designated

PDs must have completed HT Act training, either through completion of accredited HTA training, attendance at the University's HT Act training or completion of the MRC e-learning 'Research and human tissue legislation' course.

The MRC e-learning 'Research and human tissue legislation' course can be accessed via the link below:
http://www.byglearning.co.uk/mrcrsc-lms/course/category.php?id=1

8.3 Research Governance

Members of the Research Governance Team must have completed HT Act training, either through completion of accredited HTA training, attendance at the University's HT Act training or completion of the MRC e-learning 'Research and Human Tissue Legislation' course.

8.4 Research Staff and Students

Attendance at HT Act training is mandatory for all staff and students working with relevant material, and refresher training will be required every three years. The University delivers HT Act training to staff and students involved in HT Act related research and maintains a central register of all those who have attended this training**.** Certificates are issued to those who have attended. The Research Governance Team are responsible for the provision of the HT Act training and a minimum of 10 sessions during term-time are scheduled per year. Additional training sessions are provided as and when required. As part of the induction for post-graduate students in the School of Medicine, Dentistry and Biomedical Sciences the DI of the relevant licenced area provides an overview of the HT Act and the associated requirements.

Research Governance also arranges relevant courses relating to informed consent and co-ordinates access to the Good Clinical Practice (GCP) e-Learning tool, which contains a module on the informed consent process. Records of GCP completion are maintained by the Research Governance Team.

Other training courses available include:

- Research Ethics for University Staff;
- MRC e-learning 'Research and human tissue legislation';
- Good Practice in Research.

The University has a number of Health and Safety training courses which are available here:

https://www.qub.ac.uk/directorates/EstatesDirectorate/UniversitySafetyService/SafetyTraining/

Although Research Governance maintain a central register of all those who attend the University's HT Act training, staff and students are advised to also retain a personal training log.

8.5 Commercial Companies

Attendance at HT Act training is mandatory for all commercial company staff working with relevant material when the companies are operating on University premises

under the University's HTA Research Licences. Refresher training will be required every three years. The University shall delivers HT Act training to commercial company staff involved in HT Act related activities and maintains a central register of all those who have attended this training**.** Certificates are issued to those who have attended.

8.6 Anatomy Staff and Students

Training sessions on the legislative aspects of the Anatomy Licensed Area are provided by the DI to demonstrators and clinical demonstrators who will be supporting teaching within the dissecting room areas.

All registered students attending classes within the dissecting rooms, receive an induction into the Anatomy Licensed Area, at the beginning of the relevant module. This induction is led by the DI or by PDs, and covers the dedicated Anatomy Dissecting Room Code of Practice for the area. Medical and dental students are also required to sign an agreement indicating that they will comply with the requirements of HT Act.

9. Corporate Risk Management

The University has a corporate risk plan for potential serious breaches of the HT Act. The corporate risk plan details the escalation process, current control measures, additional actions for improving the management of the risk and assurance mechanisms for the University. The corporate risk plan is reviewed on a bi-annual basis and considered by the University's Risk Management Committee. Each School/Centre also has a Business Continuity Plan in place which outlines the risk for human tissue holdings.

10. References

Code A: Guiding Principles and the fundamental principle of consent
https://www.hta.gov.uk/codes
(last accessed September 2025)

Code B: Post-mortem examination and Standards
https://www.hta.gov.uk/codes
(last accessed September 2025)

Code C: Anatomical examination and Standards
https://www.hta.gov.uk/codes
(last accessed September 2025)

Code D: Public display and Standards
https://www.hta.gov.uk/codes
(last accessed September 2025)

Code E: Research and Standards
https://www.hta.gov.uk/codes
(last accessed September 2025)

Code F: Donation of solid organs and tissue for transplantation
https://www.hta.gov.uk/codes
(last accessed September 2025)

Code G: Donation of Allogenic bone marrow and peripheral blood stem cells for transplantation

https://www.hta.gov.uk/codes
(last accessed September 2025)

Human Tissue Authority definition of relevant material
https://www.hta.gov.uk/guidance-professionals/hta-legislation/relevant-material-under-human-tissue-act-2004 (last accessed September 2025)

Regulations Relating to Research Involving Human Participants
https://www.qub.ac.uk/Research/Governance-ethics-and-integrity/Research-integrity/PoliciesRegulationsandSOPs/RegulationsPoliciesandGuidelines/ (last accessed September 2025)

Policy on the Ethical Approval of Research
https://www.qub.ac.uk/Research/Governance-ethics-and-integrity/Research-integrity/PoliciesRegulationsandSOPs/RegulationsPoliciesandGuidelines/ (last accessed September 2025)

Code of Conduct and Integrity in Research
https://www.qub.ac.uk/Research/Governance-ethics-and-integrity/Research-integrity/PoliciesRegulationsandSOPs/RegulationsPoliciesandGuidelines/ (last accessed September 2025)

Queen's University Belfast HTA SOPs
http://www.qub.ac.uk/Research/Governance-ethics-and-integrity/Human-tissue/
(last accessed September 2025)

QUB Research Governance
http://www.qub.ac.uk/Research/Governance-ethics-and-integrity/ (last accessed September 2025)

QUB Health and Safety Services
https://www.qub.ac.uk/directorates/EstatesDirectorate/UniversitySafetyService/ (last accessed September 2025)

QUB University Committees
https://www.qub.ac.uk/about/Leadership-and-structure/university-governance/committee-directory/ (last accessed September 2025)

11. Contacts

11.1 MBC BCH Licence

Designated Individual (DI)			
Prof Jackie James	DI MBC/BCH	0289097 5781	j.james@qub.ac.uk
Persons Designated (PD)			
Prof Michael Tunney	PD Pharmacy	0289097 2705	m.tunney@qub.ac.uk
Prof Brian Green	PD Biological Sciences	0289097 6541	b.green@qub.ac.uk
Dr Simon Cameron	PD Biological Sciences	0289097 6421	S.Cameron@qub.ac.uk
Dr Helen Groves	PD Wellcome-Wolfson Institute for Experimental Medicine (WWIEM)	0289097 2601	h.groves@qub.ac.uk
Dr Denise McDonald	PD Wellcome-Wolfson Institute for Experimental Medicine (WWIEM)	0289097 6471	d.mcdonald@qub.ac.uk
Dr Chris Watson	PD Wellcome-Wolfson Institute for Experimental Medicine (WWIEM)	0289097 6478	chris.watson@qub.ac.uk
Dr Tom Waterfield	PD Wellcome-Wolfson Institute for Experimental Medicine (WWIEM)	0289615 0241	t.waterfield@qub.ac.uk
Dr Claire Lewis	PD The Patrick G Johnston Centre for Cancer Research (PGJCCR) /NIB	0289097 2804	claire.lewis@qub.ac.uk
Dr Kienan Savage	PD Patrick G Johnston	0289097 2934	k.savage@qub.ac.uk

	Centre for Cancer Research (PGJCCR)		
Dr Donna Small	PD Patrick G Johnston Centre for Cancer Research (PGJCCR)	0289097 2641	d.small@qub.ac.uk
Dr Cathal McNally	PD Patrick G Johnston Centre for Cancer Research (PGJCCR)/PMC	028 9097 2956	c.mcnally@qub.ac.uk
Dr Kostas Papageorgiou	PD School of Psychology	028 90 97 5653	K.Papageorgiou@qub.ac.uk

11.2 RVH Licence

Designated Individual (DI)			
Dr Gareth McKay	DI RVH	0289097 8958	g.j.mckay@qub.ac.uk
Persons Designated (PD)			
Dr Charlotte Neville	PD Centre for Public Health (CPH)	0289097 6454	c.neville@qub.ac.uk

11.3 Anatomy Licence

Designated Individual (DI)			
Dr Samantha Taylor	DI Anatomy	028 9097 2143	s.j.taylor@qub.ac.uk
Persons Designated (PD)			
Dr Declan McLaughlin	PD Anatomy	028 9097 2482	declan.mclaughlin@qub.ac.uk
Ms Nuala Tipping	PD Anatomy	028 9097 2132	n.tipping@qub.ac.uk
Ms Carly Huddleston	PD Anatomy	N/A	c.huddleston@qub.ac.uk
Mrs Amanda Wilson	PD Anatomy	N/A	amanda.wilson@qub.ac.uk
Ms Vija Vilcina	PD Anatomy	N/A	v.vilcina@qub.ac.uk
Bequeathal Secretary			
Mrs Sinead McCullough	Bequeathal Secretary Anatomy/PD	028 9097 2122	Sinead.mccullough@qub.ac.uk

12.4 Research Governance

Research Governance			
Mrs Louise Dunlop	Head of Research Governance	0289097 2572	l.h.dunlop@qub.ac.uk
Dr Paula Tighe	Research Governance	0289097 3861	p.tighe@qub.ac.uk

Miss Kathryn Taylor	Research Governance	0289097 3296	k.taylor@qub.ac.uk

12.5 Commercial Companies

Research Governance			
TBC – once Facilities Agreements are in place			

Appendix 1. Human Tissue Steering Group Membership

Pro-Vice-Chancellor for Research & Enterprise, or their nominee (Chair)	Professor Chris Scott, Faculty Dean of Research (MHLS)
MBC/BCH Designated Individual MBC/BCH Persons Designated	Professor Jackie James Professor Brian Green Dr Chris Watson Professor Michael Tunney Professor Kienan Savage Dr Claire Lewis Dr Kostas Papageorgiou Dr Simon Cameron Dr Donna Small Dr Cathal McNally Dr Helen Groves Dr Denise McDonald Dr Tom Waterfield
RVH Designated Individual RVH Persons Designated	Dr Gareth McKay Dr Charlotte Neville
Anatomy Designated Individual Anatomy Persons Designated	Dr Samantha Taylor Dr Declan McLaughlin Ms Nuala Tipping Ms Carly Huddleston Mrs Amanda Wilson Ms Vija Vilcina Mrs Sinead McCullough
Research Governance	Ms Louise Dunlop Dr Paula Tighe Miss Kathryn Taylor

Figure 1. Overview of the licencing structure

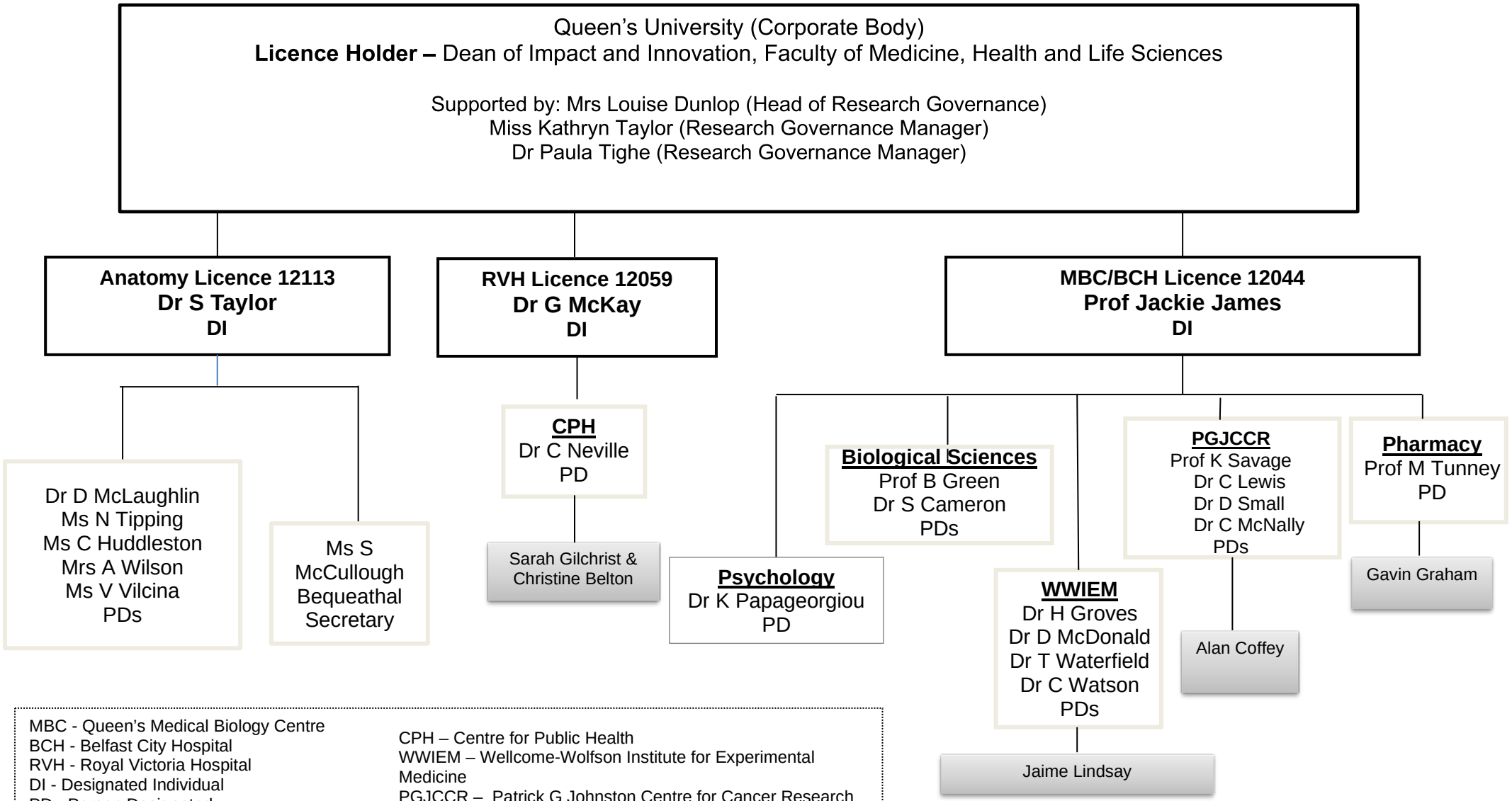

Figure 2. Overview of University Committee Structure