POLICY POL245/2

Governance Framework to Support Satellite Site Applications for the Quality in Organ Donation Research Project

This Policy replaces *POL245/1*	**Copy Number**
	Effective: 29/05/18

Summary of Significant Changes

Complete re-write of policy.

Policy

Purpose of this Document

This document has been developed to detail the NHSBT governance framework for the Quality in Organ Donation project and to demonstrate the systems which are in place to ensure that the governance framework is implemented across all premises under the HTA Research Licence No.12608.

This procedure helps ensure patient safety by providing a governance framework for the Quality in Organ Donation project.

1. Quality in Organ Donation (QUOD) Research - Background

The primary aims and objectives of the QUOD Research project are:

- To increase the number and quality of transplantable organs in the UK; and
- To improve function after transplantation and increase graft survival

The QUOD Research project aims to improve understanding of the mechanisms of injury to deceased donor organs, identify biomarkers that can be used to predict the outcomes of transplant and establish a platform to test new approaches to ameliorating donor organ injury.

The QUOD Research project collects standardised specimen samples including blood, urine and tissue from consented donors at different time points during the organ donation process and correlates this biological, clinical and demographic data to outcomes following transplantation.

The QUOD Research Biobank is within the existing Oxford Radcliffe Biobank (ORB) which is a long-established facility providing a secure and sustainable environment in which to facilitate the logistics, transportation and storage of biomaterial.

The table below details the current in scope QUOD samples and the collection points in the Organ Donation pathway.

Sample	Collection Point(s)
Blood	1. DB1 - As close to date of admission 2. DB2 - Following consent / authorisation for QUOD being obtained 3. DB3 - Prior to theatre transfer / Withdrawal of Life Sustaining Treatment 4. DB4 - Prior to cross clamp (DBD donors only)
Urine	1. DU2 - Following consent / authorisation for QUOD being obtained 2. DU3 - Prior to theatre transfer / Withdrawal of Life Sustaining Treatment 3. DU4 - Prior to perfusion / flush (DBD donors only)
Liver biopsy	Post organ retrieval
Left Kidney biopsy	Post organ retrieval
Right Kidney biopsy	Post organ retrieval
Left Ureter sample section	Post organ retrieval
Spleen section	Post organ retrieval
From Q2 2018:	
Heart biopsy from non-transplantable hearts	Taken from non-retrieved hearts or hearts procured for valves
Bronchioalveolar Lavage	Collected if cardiothoracic team in attendance

By collecting these samples and matching the results with clinical donor and recipient variables, the researchers are able to perform both prospective and retrospective analyses to identify novel markers to predict organ injury and survival.

2. Licensable Activities for NHSBT

Within England, Wales and Northern Ireland the Human Tissue Act 2004 legislates the removal, use and storage of relevant material which consists of, or includes human cells, for example organs and tissues, for scheduled purposes. These activities are regulated by the HTA via the issue of licences and inspections of related premises. The Human Tissue Act 2004 (the Act) states that the premises where the removal takes place must be licensed.

QUOD samples collected from deceased organ donors constitute relevant material under the HT Act 2004 and this activity is therefore licensable outside of Scotland.

The NHSBT Designated Individual, the Director of Quality has responsibility for overseeing compliance with the HTA Act and all associated regulations, Codes of Practice and Directions. The governance framework that supports the NHSBT Designated Individual in maintaining effective oversight is documented in POL120, HTA Governance Framework. The governance arrangements for QUOD are integrated into this framework.

The collection of QUOD samples from deceased organ donors takes place in critical care / emergency care areas and theatre suites located in NHS hospitals (donor hospitals) which are not NHSBT premises.

NHSBT Specialist Nurses for Organ Donation (SN-ODs) obtain consent (or authorisation in Scotland) for QUOD related research from donor families and facilitate the collection of the relevant blood and urine samples prior to the donor being transferred to theatre.

The National Organ Retrieval teams (NORS) who are commissioned by NHSBT collect the relevant biological fluid samples and tissue biopsy specimens during organ retrieval in theatre and return the QUOD samples to the regional QUOD centre.

3. HT Act 2004 Licensing Approach to Support QUOD

Under the HT Act 2004, NHSBT holds a Research licence (HTA licence number 12608) to cover the procurement activities carried out within the Dedicated Donation Suite at the Speke site in Liverpool.

NHSBT complies with the HT Act 2004 for the collection of samples for QUOD through the extension of the NHSBT Research licence (HTA No.12608) and include, as satellite sites, specific areas in targeted hospitals.

The Trusts / Health Boards that hold satellite site licence extensions represent those Trusts / Health Boards in England, Northern Ireland and Wales which have historically demonstrated the greatest potential for organ donation.

4. Quality Assurance in NHSBT

NHSBT has a specific governance framework to provide assurance with HTA regulatory requirements. This is documented in Policy document POL120 – NHSBT HTA Governance Framework.

The NHSBT Quality Management System (QMS) comprises operating manuals and detailed process documentation and is supported by the QPulse system. The QMS ensures continued, demonstrable compliance with a wide range of regulatory requirements which enables NHSBT to maintain its licences and accreditations. In support of this it also ensures that staff are adequately qualified, trained and competent.

Operational protocols for the consent or authorisation of donor families and sample collection for QUOD are developed and managed within the framework of the NHSBT Quality Management System. Operational protocols are developed by operational practitioners and subject to risk assessment, peer and QA review prior to training or implementation.

All users of the QUOD operational protocols are trained in their use prior to implementation and training records are maintained.

QUOD activity under HTA licence 12608 will be audited on a 2/3 yearly cycle and cover all regulated activities at all licensed sites.

The QMS and Quality Assurance process are owned by the NHSBT Director of Quality, who reports to the Chief Executive (Corporate Licence Holder) on regulatory issues and attends the Governance and Audit Committee (GAC). Assurance is delivered through:

- A quarterly Management Quality Report to the Executive Team with copy to the GAC and with an annual summary report to the Board
- Monthly monitoring of performance, via the Board performance report, against any agreed strategic objectives and targets for quality management
- Monthly reporting of supporting key operational KPIs (to the Board and Executive Team) designed to monitor that key processes remain in control
- DI oversight via the HTA Governance Framework

In order to fulfil the statutory licensing obligations for QUOD, NHSBT has established the necessary controls to ensure that suitable persons are working under the licences and all staff involved in undertaking the licensed activities are working under the direction of the Designated Individual (DI). This has been achieved through the appointment of the ODST Regional Managers and the National Quality Manager for ODT assuming the responsibilities of Persons Designated for the satellite site premises and the QUOD activities undertaken on these premises.

The persons best suited to undertake the PD role for the regional SN-OD teams are the existing ODST Regional Managers. These Regional Managers already have line management responsibility for the SN-ODs including management oversight of all donor related activity, are directly employed by NHSBT and are therefore able to ensure all governance requirements are met and report any incidents of non-compliance.

The National Quality Manager for ODT assumes the Persons Designated responsibilities for the activities of the NORS retrieval teams through the establishment of a clear communication pathway and structured training programme for the regulatory compliance aspects of the project.

Incident Reporting within NHSBT is subject to a defined management and reporting process that is linked to the QMS and supported by QPulse. Incidents arising as a result of QUOD are reported using QPulse and managed within the existing procedures for incident reporting.

QUOD is now an established procedure in NHSBT and governance is overseen as a standing agenda item at ODT CARE and reports of QUOD incidents and statistics are provided for advisory group meetings, including ODTs Research Innovation and Novel Technologies Advisory Group (RINTAG).

5. Procedural Controls

All NHSBT QUOD procedural primary and secondary documents should be subject to a minimum annual review. This annual review should include input and feedback from the QUOD team at Oxford. Similarly reviews and updates to the QUOD procedural primary and secondary documents which are owned and maintained by the University of Oxford should include input and feedback from the National Quality Manager – ODT (from a regulatory perspective) and if appropriate from the NHSBT ODT Research Manager (from an operational perspective where appropriate).

Additionally INF1081 and DAT2447 will be subject to a minimum annual review with the ODT Persons Designated and ODST teams to ensure that the areas named within the satellite site licences are accurate and current.

The procedures for collection of additional tissue samples (non-transplantable hearts and bronchioalveolar lavage samples) are currently being developed following agreement with the Cardio Thoracic Advisory Group (CTAG).

6. Governance - Personnel

6.1 Regulatory Framework

Quality Assurance Team

The ODT Quality Assurance team will be trained in the HT Act 2004 and the HT Act (Scotland) 2006 and more specifically in those aspects of the legislation, standards and codes of practice which are applicable to QUOD.

National Organ Retrieval Service / Scotland Organ Retrieval Teams

All abdominal retrieval teams across England, Wales, Northern Ireland and Scotland will carry out e-learning annual training in the regulatory framework to support QUOD and their responsibilities under the licence. The Scotland Organ Retrieval Team will receive this training for those occasions when they collect QUOD samples from consented donors in licensed hospitals across England, Wales and Northern Ireland.

NHSBT Persons Designated

All nominated Persons Designated under the NHSBT Research Licence 12608 will undertake annual update training in the regulatory framework to support QUOD and in the role of the Person Designated.

NHSBT Specialist Nurses in Organ Donation

All Specialist Nursing teams across England, Wales and Northern Ireland will receive annual update training in the regulatory framework to support QUOD and their responsibilities under the licence.

6.2 Ad hoc Regulatory Training

Ad hoc regulatory update training will be provided to any individual or group working under the governance of the NHSBT licensing framework of Research licence 12608 either:

- In response to an incident or an identified incident trend;
- In the event of a change to the legislation / Regulations / Codes of Practice / Directions

Evidence of regulatory training, whether periodic or ad-hoc, will be documented on Supplementary Training Records (FRM953).

6.3 Procedural Update Training

Training will be provided in the event of a procedural change. Depending on the nature / extent of the procedural change the update training will be provided either:

- Via the Quality Leads / QUOD Leads for each Organ Donation Services teams;
- Self taught.
  Evidence of procedural training updates will be documented on Task Based Training Records (FRM511)

7. Communications

7.1 HTA

Communications with the HTA relating to the Licensing including lobbying for a change to the licensing framework for Research will be led by the Designated Individual.
Internal communications relating to the licensing aspects of QUOD will be led by the National Quality Manager for ODT. This will also include an update on the regulatory aspects of QUOD at the NHSBT DI meeting forum.

7.2 National Organ Retrieval Service / Scotland Organ Retrieval Teams

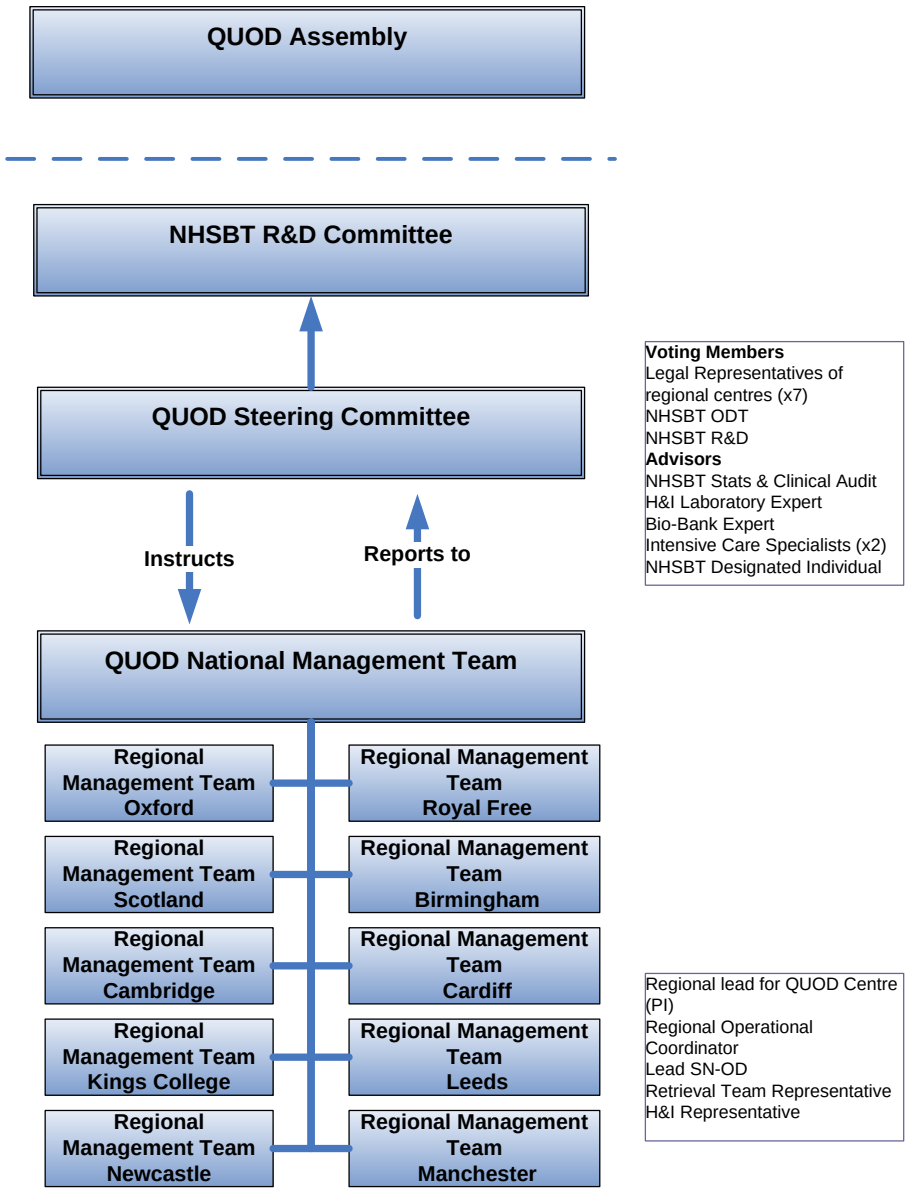
The governance framework for QUOD requires that there are regular communications from the Persons Designated to anyone working under the HTA Research Licence 12608. This includes the NORS teams for the procurement of relevant material for QUOD in theatre.
The communication route from PD to the NORS representatives will be via a standing agenda item with an open Q&A session at the QUOD Consortium meetings.

8. Annual Activity Reporting

As a licensed establishment, NHSBT is required to submit annual reports of the licensed activity undertaken. The source of the data for the annual data returns is the QUOD database which is owned and managed by the QUOD team at Oxford.
The data requirements for annual reporting under a Research licence are confirmed by the Human Tissue Authority.

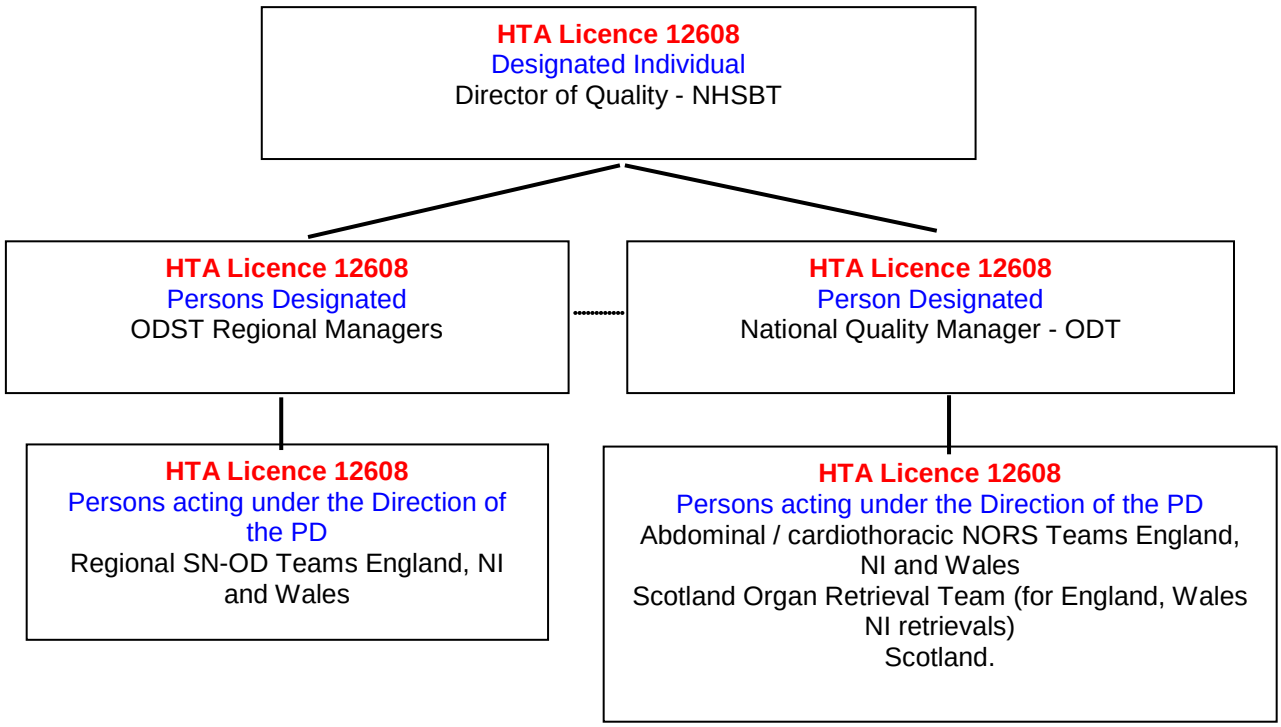
Appendix A – QUOD Governance

The QUOD Research project is led by a National Consortium of experts from the fields of organ donation, organ transplantation and associated clinical, scientific and regulatory disciplines. It has its own governance and reporting structure as illustrated below. The 7 Regional Management Teams are based on the current configuration of abdominal organ retrieval teams (NORS) across England, Scotland, Northern Ireland and Wales.



Appendix B – Designated Individual Supervisory Governance Structure

The schematic below illustrates the governance arrangements to ensure oversight of licensed activities at the satellite sites.



Appendix C – QUOD Governance alignment to NHSBT Governance

The schematic below illustrates how the regulatory reporting structure for QUOD aligns to the QUOD governance structure.