POLICY POL245/1

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

This Policy replaces *Uncontrolled Version 1.1 09/09/2014*	**Copy Number**
	Effective **10/02/16**

Summary of Significant Changes

N/A

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.

1. NHSBT Background

NHS Blood and Transplant (NHSBT) was established as a Special Health Authority in October 2005. Its remit is the provision of a safe, reliable, efficient supply of blood, tissues and organs and associated services to the NHS.

NHSBT provides blood related services throughout England and North Wales.

NHSBT Tissue Services within the Diagnostics and Therapeutic Services (DTS) Directorate is the UK's major provider of human tissue for transplant. The role of Tissue Services is to co-ordinate, procure, process, store and supply human tissue grafts for use in surgery within the National Health Service (NHS) and independent hospitals in the UK. NHSBT Tissue Services has its main Tissue Banking facility at Speke in Liverpool.

The Organ Donation and Transplantation (ODT) Directorate within NHSBT has responsibilities as the organ procurement organisation for the United Kingdom. ODT manage the NHS Organ Donor Register and provide a dedicated 24 hour service that assists with the identification, referral and facilitation of organ donation from deceased donors and ensures that donated organs are matched and allocated to patients in a fair and transparent way.

The Directorate has a main office site at Stoke Gifford in Bristol and also has twelve regional Organ Donation Services teams throughout the UK, South East, South Central, South West, South Wales, London, Eastern, Midlands, North West, Yorkshire, Northern, Scotland and Northern Ireland.

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.

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

Despite advances in drug management, surgical technique and post operative care, improvements in organ and patient survival following transplantation have not significantly improved over the last decade. In addition, the improved ICU management of trauma patients and patients who have suffered from cerebral injury means that the number of good quality organs donated is expected to decline.

To address this, the transplant community has been turning to organ donors previously considered unsuitable for donation.

By improving the quality of organs procured from marginal donors, organs previously discarded or rejected as unsuitable may be used for transplantation and the long term outcomes for transplant recipients should be improved.

The primary aims and objectives of the QUOD Research project which are to be realised once the future research studies are undertaken 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.

To achieve this, the QUOD Research project has been established to collect standardised specimen samples including blood, urine and tissue from consented donors at different time points during the organ donation process and to correlate this biological, clinical and demographic data to outcomes following transplantation.

The first phase of this project has been the establishment of a national biobank resource at the University of Oxford and associated governance structures and operational and logistical protocols to enable samples to be collected.

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

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.

The output from these analyses is available to inform and facilitate novel therapeutic strategies to preserve and inform organ quality.

3. 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.

Currently, the activity of ‘removal’ under the Act is an activity which is specific to either a Removal, Post Mortem or Research licence. For QUOD, the samples collected from deceased organ donors constitute relevant material under the HT Act 2004 and this activity is therefore licensable.

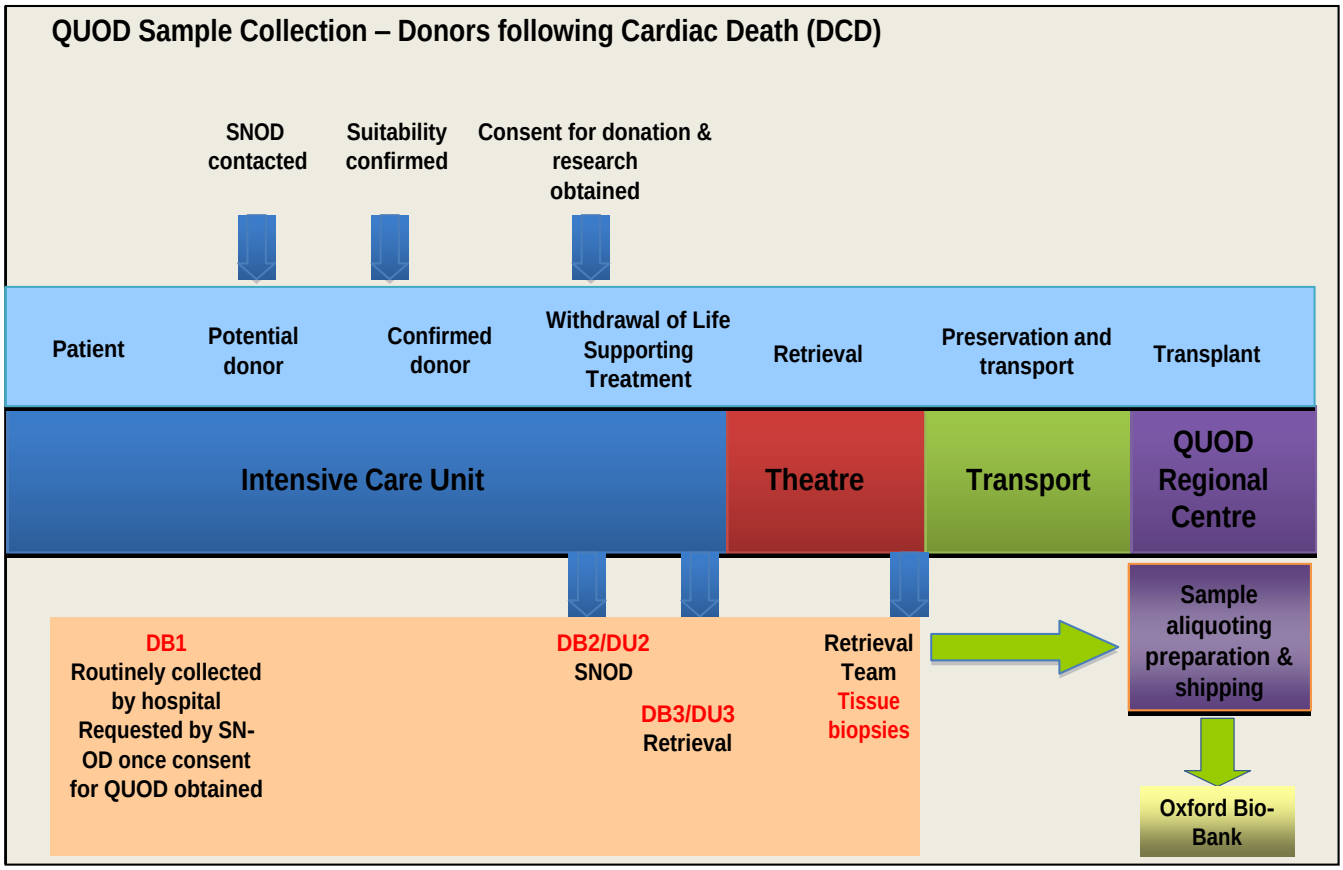
The NHSBT Designated Individual, the Director of Quality has responsibility for overseeing compliance with the HTA Act and all associated regulations, Codes of Practice and Directions. The governance framework that supports the NHSBT Designated Individual in maintaining effective oversight is documented 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 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 blood and urine samples and tissue biopsy specimens during organ retrieval in theatre and return the QUOD samples to the regional QUOD centre.

The diagrams overleaf illustrate the QUOD sample collection points within the organ donation and retrieval high level process for Donors following Brain Death (DBD) and Donors following Cardiac Death (DCD).



4. 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.

Following proposals by the Department of Health and the HTA, 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 to be targeted for 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.

Whilst it is not anticipated at this stage, the Designated Individual (DI) for the NHSBT Research Licence No.12608 may in the future give approval for other material and / or other research programmes to be included within the scope of the satellite site licences. If this were to be agreed it would be completed via a formal, controlled change management process.

5. Implementation and Licence Application Approach

The implementation activities to enable the satellite site licences to be granted and QUOD sample collection protocols to be implemented across the targeted Trusts / Health Boards which was executed in 3 discrete phases.

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NHSBT has formally approached each of the Trusts / Health Boards to discuss the licensing proposal to include specific areas within each Trust / Health Board as satellite premises under the scope of the NHSBT Research licence.

On receipt of written approval from each Trust / Health Board for the licensing proposal, NHSBT has prepared and submitted satellite site applications for each premise to the HTA.

Satellite site applications to the HTA have been submitted in batches which are broadly aligned to the Trusts / Health Boards which are in scope for each implementation phase.

With the first application for satellite site licences, NHSBT also submitted the overarching evidence to demonstrate how each satellite site links to the governance of the hub (this document).

On completion of the implementation activities to support QUOD sample collection across the 41 in scope hospitals, the QUOD programme has transitioned from a project to a “Business as Usual” phase. The additional arrangements to support Business as Usual governance of QUOD are detailed in section 9.

6. Quality Assurance in NHSBT

NHSBT's operational activities are subject to extensive regulation and to support this a comprehensive Quality Management System (QMS) has been developed.

The regulation of activities within the Blood Components supply chain, including activities within RCI, is covered by the Blood Safety and Quality Regulations (BSQR) and takes into account the requirements of the relevant European Directives. The MHRA is the Competent Authority under the BSQR. These legally binding requirements are captured in the Guidelines for the Blood Transfusion Service in the UK (Red Book) along with additional guidance from the Joint United Kingdom Blood Transfusion Services and National Institute of Biological Standards and Control Professional Advisory Committee (JPAC) as noted above.

Where applicable, regulation of activities within ODT, Tissues, Stems Cell and H&I is covered by the Human Tissue Act 2004, EU Tissues and Cells Directives and the Quality and Safety of Organs Intended for Transplantation Regulations 2012 and is regulated by the Human Tissue Authority. Compliance with Clinical Pathology Accreditation (CPA) and Joint Accreditation Committee – ICST & EBMT (JACIE) standards is also required to operate in some of these areas. Compliance with ISO13485 is required in order for NHSBT to CE mark the reagents that are supplied for Quality Assurance purposes and Underwriters Laboratories (UL) inspects regularly to verify compliance in this area.

As a supplier of critical, life saving services, and in common with private sector industries such as pharmaceuticals or food, NHSBT operates a single comprehensive extensive Quality Management System (QMS) across blood, specialist services, tissues and organ donation and transplantation directorates which is designed to ensure the supply of safe blood, tissues and organs and compliance with regulation.

Within the QMS a specific governance framework has been developed to assure HTA regulatory compliance. This is documented in Policy document POL120 – NHSBT HTA Governance Framework.

The NHSBT 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 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. Operational protocols are reviewed on an annual basis or earlier if operational practice requires it.

All users of the QUOD operational protocols are trained in their use prior to implementation and training records are maintained. The training in the operational protocols for QUOD has been closely aligned to the implementation plan for each phase to ensure that the training is relevant and timely.

Adherence is monitored through a comprehensive schedule of self inspection which provides important assurance regarding operational performance and regulatory compliance. Within NHSBT Quality Assurance staff lead and manage the NHSBT self inspection schedule. Audits are programmed on a 2/3 yearly cycle and cover all regulated activities at all licensed sites. The NHSBT self inspection schedule has been extended to include the licensed activities undertaken at QUOD satellite site premises under the governance of the NHSBT licence No.12608.

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 for incident reporting. Incidents arising as a result of QUOD are reported using QPulse and managed within the existing procedures for incident reporting.

7. Human Tissue Authority Standards to Support QUOD

Human Tissue Authority Standards		
Consent		
C1	Consent is obtained in accordance with the requirements of the HT Act 2004 and as set out in the Codes of Practice.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☒ Fully met or exceeded
Please provide examples. Consent is gained by the Specialist Nurse for Organ Donation (SN-OD) in accordance with the requirements of the HT Act 2004. Specialist Nurses follow internal NHSBT procedures (MPD901 – Approaching the family regarding Organ and Tissue Donation / MPD902 – Consent Conversation for Organ and / or Tissue Donation) and record the consent conversation on Consent Form FRM4210. Consent for Organ and / or Tissue Donation is governed by Policy POL164.		
C2	Information about the consent process is provided and in a variety of formats.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☒ Fully met or exceeded

Please provide examples. Information regarding Organ and Tissue Donation and scheduled purposes is shared with the donor family in leaflet format. These leaflets are made available to the family at the time of the consent conversation or at any time after the donation. These leaflets are available in a number of different languages and if required, NHSBT has access to translation services. Updated versions of these leaflets will be available publically on the NHSBT Organ Donation website from 01/11/13.		
C3	Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☒ Fully met or exceeded
Please provide examples. Specialist Nurses for Organ Donation receive a 2 day intensive training course in consent as part of their induction training. All SN-ODs receive a 1 day annual update training in advanced consent.		

Governance and Quality Systems

GQ1	All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☒ Fully met or exceeded
Please provide examples. As part of the NHSBT Quality Management System, all policies and procedures are documented, validated and approved prior to formal training and operational use. The procedural documentation is developed by practitioners of the process and peer reviewed by other practitioners and Quality Assurance teams. They are reviewed either on an annual basis or in line with operational change in practice. NHSBT policies and procedures are managed and controlled within the corporate document management system – QPulse.		
GQ2	There is a documented system of quality management and audit.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☒ Fully met or exceeded
Please provide examples. A Quality Management System has been implemented within the NHSBT Organ Donation and Transplantation Directorate in compliance with the Quality and Safety of Organs Intended for Transplantation Regulations 2012. The Quality Management System within ODT includes the elements of Document Management, Training, Incident Reporting, Audit and the Assessment and Management of Risk. The Quality Assurance team which has been established to support ODT works across the 13 operational areas of the Directorate and comprises a National Quality Manager for the Directorate, a Quality Assurance Manager, an Assistant QA Manager and a QA Administrator. This team reports to the Associate Director for Quality who is the Designated Individual for all NHSBT regulatory licences, including those governed by the HTA. . Systems for Audit and Incident reporting have been established ensuring incidents are fully investigated and that lessons learnt are reflected back into operational practice. Within the ODT Directorate, the Quality Assurance and Clinical Governance teams work together to ensure patient safety and lessons learned are taken on board. The HTA governance structure for NHSBT's Research licence and the linked satellite site licences is documented in Policy document POL120.		

GQ3	Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☒ Fully met or exceeded

Please provide examples.

The Specialist Nurses for Organ Donation undergo comprehensive learning and development programmes in the operational and regulatory aspects of their work. Following intensive induction training, Specialist Nurses for Organ Donation then receive annual update training in core aspects of their work.
Changes to operational procedures and / or regulatory practice are introduced under change control and training is delivered in the changes prior to operational implementation.

The National Organ Retrieval Services teams are trained annually in regulatory and operational practice relevant to this licence.

GQ4	There is a systematic and planned approach to the management of records.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☒ Fully met or exceeded

Please provide examples.
As an organisation NHSBT has an established system for the management and storage of records (SPN189 – NHSBT Record Storage).
Within the ODT directorate, there are established documented procedures for Proceeding and Non Proceeding Donor File Management (SOP3859 – Management of the Donor File / INF1001 – Contents of the Donor File) and for subsequent archiving of donor files (SOP3863 – Management of Archived Donor Files).

GQ5	There are documented procedures for distribution of bodies, body parts, tissues or cells.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☒ Fully met or exceeded

Please provide examples.

NHSBT Specialist Nurses for Organ Donation (SN-ODs) obtain consent 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 NORS teams who are commissioned by NHSBT collect the relevant blood and urine samples and tissue biopsy specimens during organ retrieval in theatre and return the QUOD samples to a regional QUOD centre.

At the regional QUOD centre, the samples are processed and stored intermediately pending onward transportation to the Oxford Radcliffe Biobank (ORB) for final processing and long term storage. The Oxford Radcliffe Biobank (ORB) is licensed for Research under HTA licence No.12217.

The scope of the NHSBT licensed activities for the satellite sites linked to Research licence No.12608 is limited to the consent and removal of relevant material i.e. the collection of QUOD samples within the donor hospital. All other licensable activities are governed under the University of Oxford (ORB) Research licence No.12217.

The licensing boundaries and governance arrangements across the QUOD sample collection pathway are documented in a contract between NHSBT and the University of Oxford.

GQ6	A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☒ Fully met or exceeded

Please provide examples.
NHSBT has a system for allocating a unique 6 digit number to each donor. Similarly the QUOD samples are each individually bar coded.

The 6 digit donor number will act as the link between the donor record and the QUOD samples collected thus enabling end to end and reciprocal traceability of the samples.

GQ7	There are systems to ensure that all adverse events and/or incidents are investigated promptly.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☒ Fully met or exceeded

Please provide examples.
NHSBT ODT has an established management system for the reporting, investigation and closure of incidents. SOP3888 – Reporting an Organ Donation / Transplantation Incident to NHSBT and SOP3842 – Reporting and Managing Incidents in Organ Donation and Transplantation give details of how to report incidents, the timeframes in which incidents should be reported and when follow up reports are required. The QUOD Sample Collection protocol (SOP4044 – Consent / Authorisation and Collection of Samples for Quality in Organ Donation Research – Specialist Nursing role) instructs the user to report any incidents through the existing system and associated protocols.

The training programme for the NORs teams includes training in SOP3888.

GQ8	Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☒ Fully met or exceeded

Please provide examples.
NHSBT has an established management system in place for the assessment and management of risks. The Senior Management Team of each Directorate manages and monitors their risks on a regular basis. Within the ODT Directorate, each local team has a risk register which is reviewed and monitored on a regular basis.
Procedures detailing the activities for QUOD have been risk assessed.

Premises, Facilities and Equipment

PFE1	The premises are fit for purpose.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☒ Fully met or exceeded

Please provide examples.
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. These premises are licensed as satellite sites under the Research licence (HTA No.12608) held for NHSBT premises in Speke, Liverpool.

NHSBT has demonstrated the governance arrangements for each satellite site within the satellite site application.

Blood and urine samples are taken as standard practice within hospital procedures in critical care and emergency care areas of these hospitals and similarly blood, urine and tissue samples are collected as standard from hospital theatre suites. QUOD does not propose to collect any sample types from patients / donors under the care of these clinical areas that are outwith routine hospital practice.

PFE2	Environmental controls are in place to avoid potential contamination.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☒ Fully met or exceeded
Please provide examples. The removal of relevant material for QUOD takes place in theatre suites or critical care areas within the hospital – all of which meet applicable environmental standards. NHSBT and NORs teams are trained in how to collect and package the samples to avoid any risk of contamination.		
PFE3	There are appropriate facilities for the storage of bodies, body parts, tissues and cells.	☒ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☐ Fully met or exceeded
Please provide examples.		
PFE4	Systems are in place to protect the quality and integrity of bodies and body parts during transport and delivery to a destination.	☒ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☐ Fully met or exceeded
Please provide examples.		
PFE5	Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☒ Fully met or exceeded
Please provide examples. Equipment for the collection of blood and urine samples for QUOD is routinely used as part of hospital practice and meets the necessary standards. The tissue biopsy samples are collected by the NORs teams as part of the organ retrieval process undertaken in theatre. The University of Oxford team provide one use disposable Biopsy guns for this purpose (Biopince "full-core" biopsy device) which meets all appropriate standards.		

Disposal		
D1	There is a clear and sensitive policy for disposing of human organs and tissue.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☒ Fully met or exceeded
Please provide examples. The disposal of QUOD samples under the NHSBT Research licence is a rare occurrence as it is likely that collected samples will have already been transported to the University of Oxford. SOP4044 defines the procedure for the disposal of samples for those situations where disposal is to be undertaken whilst the samples are under the governance of the NHSBT licence, NHSBT Specialist Nurses for Organ Donation are all trained to these procedures prior to operational use.		

D2	The reasons for disposal and the methods used are carefully documented.	☐ Not applicable ☐ Not met ☐ Partially met ☐ Almost met ☒ Fully met or exceeded

Please provide examples.
SOP4044 defines the circumstances and the methods for the disposal of QUOD samples.

NHSBT Specialist Nurses for Organ Donation are all trained to these procedures prior to operational use. Details of the disposal are recorded on the QUOD worksheet supplied by the University of Oxford.

8. QUOD Risk Assessment

Risk Assessment for:
Collection of relevant material (blood, urine and tissue biopsies) from deceased organ donors in Critical Care and Theatres in specified hospital Trusts / Health Boards. This is only for use in the study entitled "Quality in Organ Donation (QUOD)" – REC Number 13/NW/0017

Purpose
This risk assessment is carried out to determine the risk of the processes carried out under satellite licences linked to Research Licence12608 held by NHS Blood and Transplant (NHSBT). It is reviewed regularly throughout the period of implementation and then annually thereafter.

Date Completed: 1st October 2013
Date of Review and Update: 9th September 2014

Person(s) who Conducted the Risk Assessment: NHSBT National Quality Manager – Organ Donation and Transplantation
Person(s) who Conducted the updated Risk Assessment: NHSBT National Quality Manager – Organ Donation and Transplantation

Background
The QUOD Research initiative 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.

To achieve this, the QUOD Research initiative aims to collect standardised specimen samples including blood, urine and tissue from consented / authorised donors at different time points during the donation process and correlate biological, clinical and demographic data to outcomes following transplantation. The first phase of this project has been the establishment of a national biobank resource at the University of Oxford and associated governance structures and operational and logistical protocols to enable samples to be collected.

The involvement of NHSBT in this initiative is in the collection of the specimen samples from consented / authorised donors. As a licensable activity under the HT Act 2004, the removal of relevant material for QUOD is only be sought and undertaken in hospital premises which are licensed as satellite site premises under the NHSBT Research licence (HTA number 12608).

The collection of QUOD samples from deceased organ donors takes place in appropriately licensed critical care / emergency care areas and theatre suites located in NHS hospitals (donor hospitals) which are not NHSBT premises. Blood and urine samples are routinely taken as part of hospital procedures in critical care and emergency care areas of these hospitals and similarly blood, urine and tissue samples are routinely collected from hospital theatre suites. QUOD does not propose to collect any sample types from patients / donors under the care of these clinical areas that are outwith routine hospital practice.

NHSBT Specialist Nurses for Organ Donation (SN-ODs) obtain consent 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 NORS teams who are commissioned by NHSBT collect the relevant blood and urine samples and tissue biopsy specimens during organ retrieval in theatre and return the QUOD samples to the regional QUOD centre.

At the regional QUOD centre, the samples are processed and stored intermediately pending onward transportation to the Oxford Radcliffe Biobank (ORB) for final processing and long term storage. The Oxford Radcliffe Biobank (ORB) is licensed for Research under HTA licence No.12217.

Note – the scope of the NHSBT activities for the satellite sites linked to Research licence No.12608 is limited to the consent and removal of relevant material i.e. the collection of QUOD samples within the donor hospital. All other licensable activities are governed under the University of Oxford (ORB) Research licence No.12217.

Risk Assessment Procedure

1) This Risk Assessment has been carried out to support the overarching licensing and governance principles of QUOD;
2) This Risk Assessment has been further supported by individual premises specific risk assessments for each satellite site application under Research licence HTA No.12608.

Risk Assessment - Governance

Risk Id	Risk Description	Impact	Likelihood	Risk Score
R1	Operational teams are not informed of regulatory changes which may result in a breach of the licence conditions **Likely Cause**: Inadequate communications through the governance channels of DI – PD – Operational Teams. **Mitigation:** Robust implementation of governance and communication channels in POL120 Attendance by DI at Organ Donation Management team meetings and onward cascade of key regulatory messages to operational teams via DI and ODT National Quality Manager.	4	2	**8**
R2	DI is not made aware of local operational change that may result in a breach of the licence conditions. **Likely Cause**: Inadequate communications through the governance channels of Operational Teams-PD-DI-HTA **Mitigation**: Clear definition provided to operational teams as part of regulatory training of what local changes need to be reported upwards through the regulatory governance channels.	2	3	**6**

Risk Assessment – Premises

As previously stated, the collection of QUOD samples from deceased organ donors takes place in appropriately licensed critical care / emergency care areas and theatre suites located in NHS hospitals (donor hospitals) which are not NHSBT premises. Blood and urine samples are taken as a standard element of hospital procedures in critical care and emergency care areas of these hospitals and similarly blood, urine and tissue samples are collected as standard from hospital theatre suites. QUOD does not propose to collect any sample types from patients / donors under the care of these clinical areas that are outwith routine hospital practice. In this context, NHSBT has assessed the overarching premises related risks and has scored them as nil risk.

Premises specific risk assessments will be undertaken and submitted to the Human Tissue Authority with each satellite site application.

Risk Assessment - Processes

Risk Assessment - Consent /Withdrawal of Consent

Risk Id	Risk Description	Impact	Likelihood	Risk Score
R3	Samples for QUOD are collected unlawfully if appropriate consent under the HT Act 2004 and associated Codes of Practice is not obtained. **Likely Cause**: Inappropriate or inadequate staff training to Specialist Nurses for Organ Donation in the specific Consent requirements for QUOD. **Mitigation**: Documented procedures for the specific consent requirements for QUOD. QUOD Consent training for Specialist Nursing teams is a mandatory deliverable prior to go live of QUOD sample collection for a team. Similarly QUOD Consent training is a mandatory deliverable for any new or returning Specialist Nurses. QUOD Consent to be documented via the Consent Form sticker on form id FRM4281,	4	1	**4**
R4	Samples for QUOD are retained unlawfully after a family has withdrawn consent. **Likely Cause**: Inadequate procedures in place to receive and act upon the family's wishes in conjunction with the Oxford Radcliffe Biobank. **Mitigation**: Documented procedures for the management of consent withdrawal for QUOD; Specialist Nurse training in Withdrawal of Consent protocols; QUOD Consent withdrawal to be documented at the appropriate time point.	3	3	**9**

Risk Assessment - Removal of Relevant Material

Risk Id	Risk Description	Impact	Likelihood	Risk Score
R5	Blood / urine / tissue biopsy samples are collected from unlicensed premises **Likely cause**: Lack of clarity within Specialist Nursing teams as to which Trusts are covered by satellite licence **Mitigation**: An Information Sheet (INF1081) managed within the NHSBT Document Management System lists all licensed hospitals and areas within the hospitals for QUOD activity.	3	2	**6**

Risk Id	Risk Description	Impact	Likelihood	Risk Score
	Non supply of QUOD sample collection boxes into unlicensed premises			
R6	Blood / urine tissue biopsy samples are collected from unlicensed areas within licensed premises **Likely causes**: Lack of clarity within Specialist Nursing teams as to which areas are covered by satellite licence; Donor is facilitated in an area of the hospital not previously identified as requiring satellite licence coverage. **Mitigation**: An Information Sheet (INF1081) managed within the NHSBT Document Management System lists all licensed hospitals and areas within the hospitals for QUOD activity. Training content to include steps to be taken by the Specialist Nurse should an unlicensed area be used to facilitate a donor. This will include the communications required to report the change to the PD, DI and HTA.	2	3	**6**
R7	Relevant material is removed for research which is not approved and listed as an approved research programme by the DI **Likely Causes**: Lack of clarity within the NORS teams as to what material for research is approved under the satellite site licence granted to NHSBT **Mitigation**: Training content to the NORs teams includes the scope of relevant material for removal for research and appropriate change control for amended scope	2	3	**6**

Risk Assessment - Traceability and Recordkeeping

Risk Id	Risk Description	Impact	Likelihood	Risk Score
R8	Samples are collected but not recorded **Likely Causes**: Inadequate training amongst SN-OD and retrieval teams of the record keeping requirements of QUOD Quod sample collection worksheet is missing from the QUOD box **Mitigation**: Operational training in the QUOD sample collection and associated record keeping protocols are a mandatory deliverable prior to go live in any regional team	4	3	**12**
R9	Samples are recorded but cannot be located **Likely Causes**: SN-ODs complete paperwork prior to samples being taken and then overlook sample collection Samples are mislaid between critical care area / theatre / Biobank	4	2	**8**

Risk Id	Risk Description	Impact	Likelihood	Risk Score
	Confusion over who is responsible for samples at any given point in the pathway **Mitigation**: Clear understanding of the boundaries of responsibility for samples Operational training in the QUOD sample collection and associated record keeping protocols are a mandatory deliverable prior to go live in any regional team and include photograph of the worksheet to be taken and emailed to the ODST office and QUOD team at Oxford			

Risk Assessment – Disposal

Risk Id	Risk Description	Impact	Likelihood	Risk Score
R10	Samples collected for QUOD are not disposed of in accordance with the conditions of the HT Act 2004 and / or the wishes of the family **Likely causes**: Lack of understanding amongst operational teams of the regulatory requirements to dispose of samples appropriately Lack of understanding amongst operational teams of the actions to be taken in the event of a family withdrawing consent Procedural documentation does not give clear instructions on how and when samples should be disposed of **Mitigation**: Disposal procedure to be documented and operational teams to receive training in disposal procedure prior to go live	4	2	**8**

9. "Business as Usual" Governance Arrangements for QUOD

The implementation activities to enable the satellite site licences to be granted and QUOD sample collection protocols to be implemented across the targeted Trusts / Health Boards have been delivered as part of an NHSBT project.

On completion of the project, the support and governance for QUOD licensed activities will transition to a Business as Usual operational model.

This section documents the "Business as Usual" governance arrangements which will be established in addition to the measures already implemented to ensure ongoing regulatory compliance.

9.1 Procedural Controls

All NHSBT QUOD procedural primary and secondary documents are managed in QPulse. The current effective version is available via the Controlled Document Library on the NHSBT Intranet.

Owner / Author roles for these documents are currently held by the same person. It is recommended that the two roles should be undertaken (as with other NHSBT ODT documents) by two separate employees.

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.

9.2 Governance - Personnel

9.2.1 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 receive annual update 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 receive 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.

9.2.2 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)

9.2.3 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)

9.3 Communications

9.3.1 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.

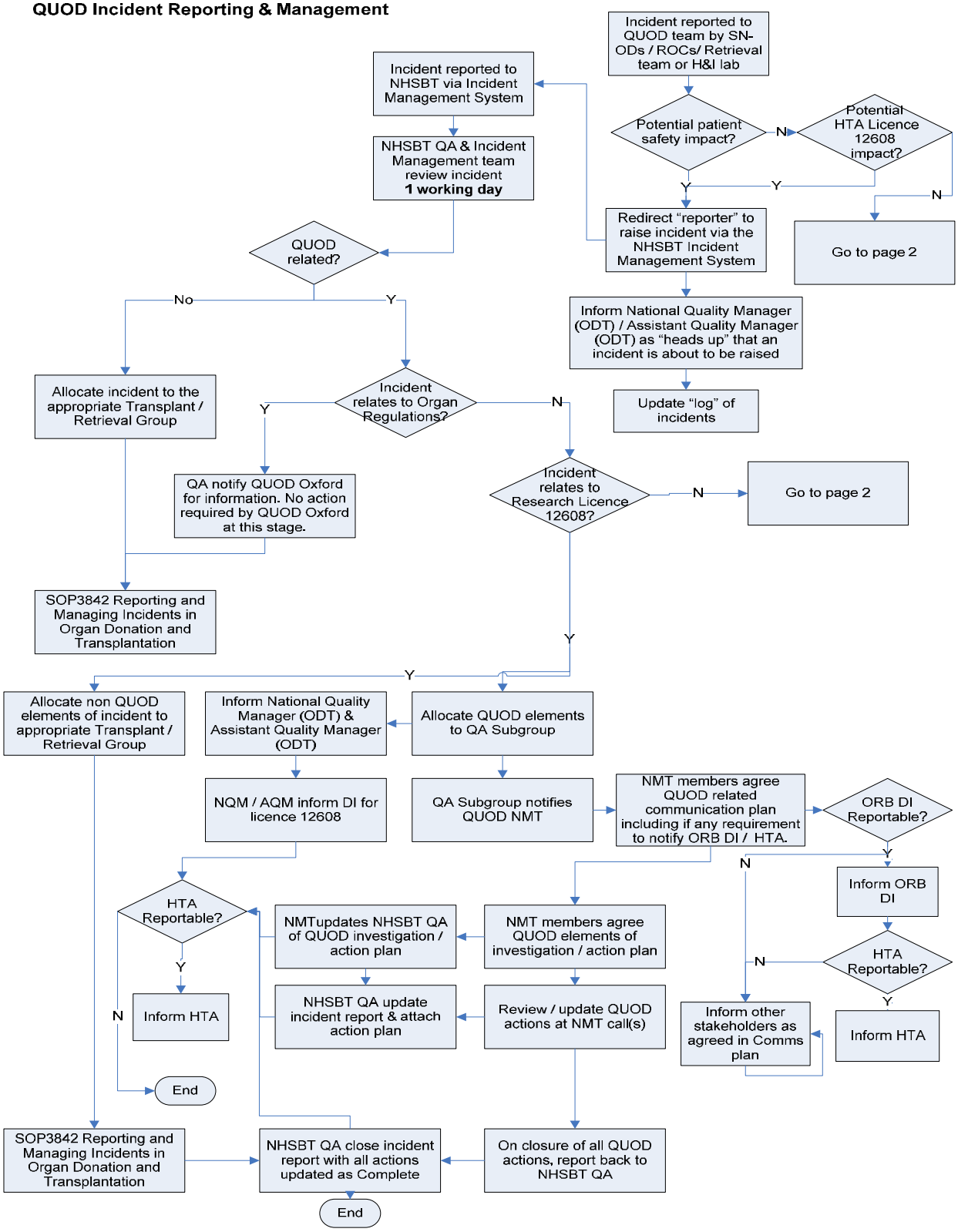
9.3.2 National Organ Retrieval Service / Scotland Organ Retrieval Teams
The governance framework for QUOD requires that there are regular communications from the Persons Designated to anyone working under the HTA Research Licence 12608. This includes the NORS and SORT teams for the procurement of relevant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

9.4 Annual Activity Reporting

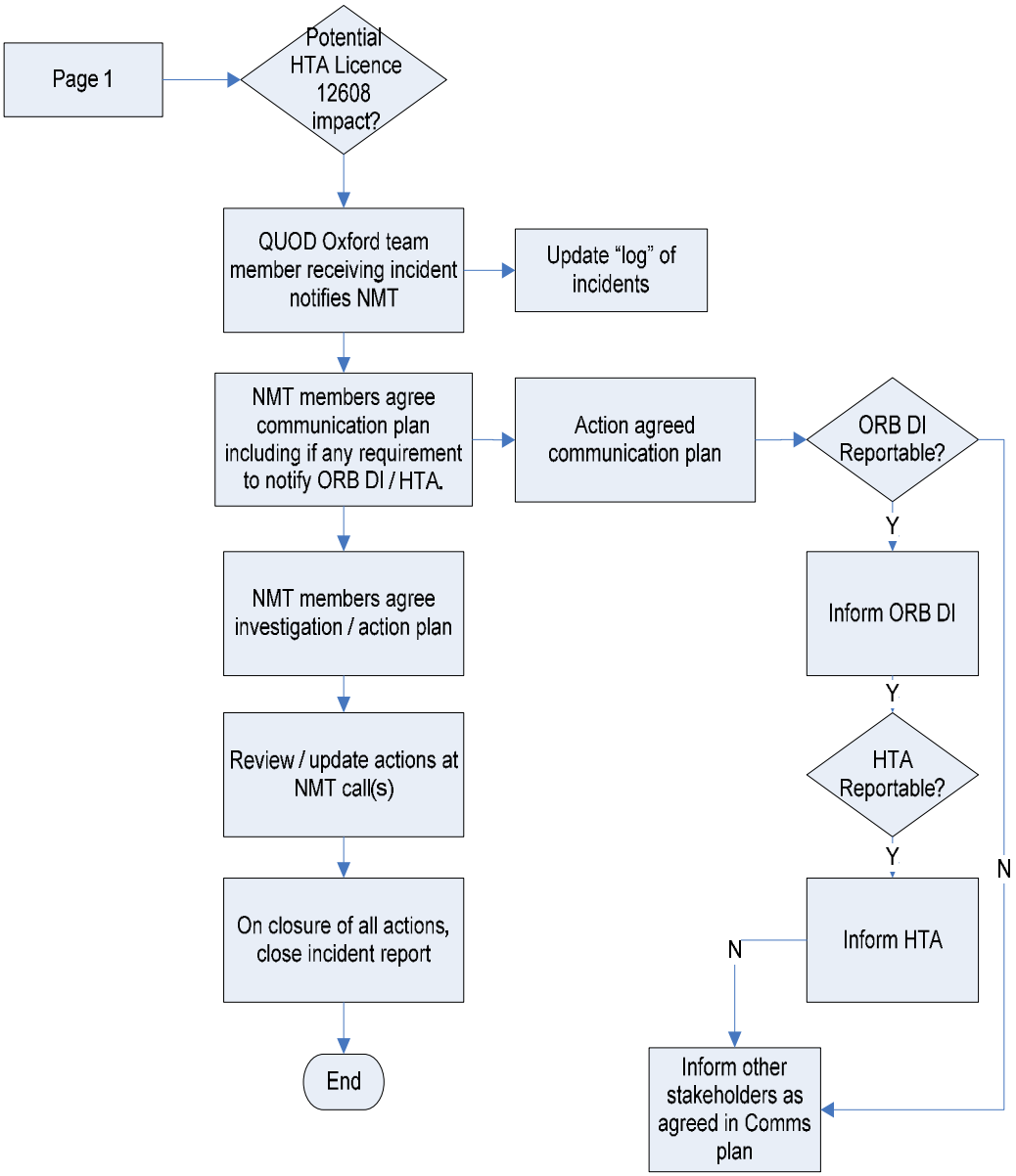
As a licensed establishment, NHSBT is required to submit annual reports of the licensed activity undertaken. The source of the data for the annual data returns is the QUOD database which is owned and managed by the QUOD team at Oxford.
The data requirements for annual reporting under a Research licence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

9.5 Reporting and Management of QUOD related Incidents

QUOD Incident Reporting & Management

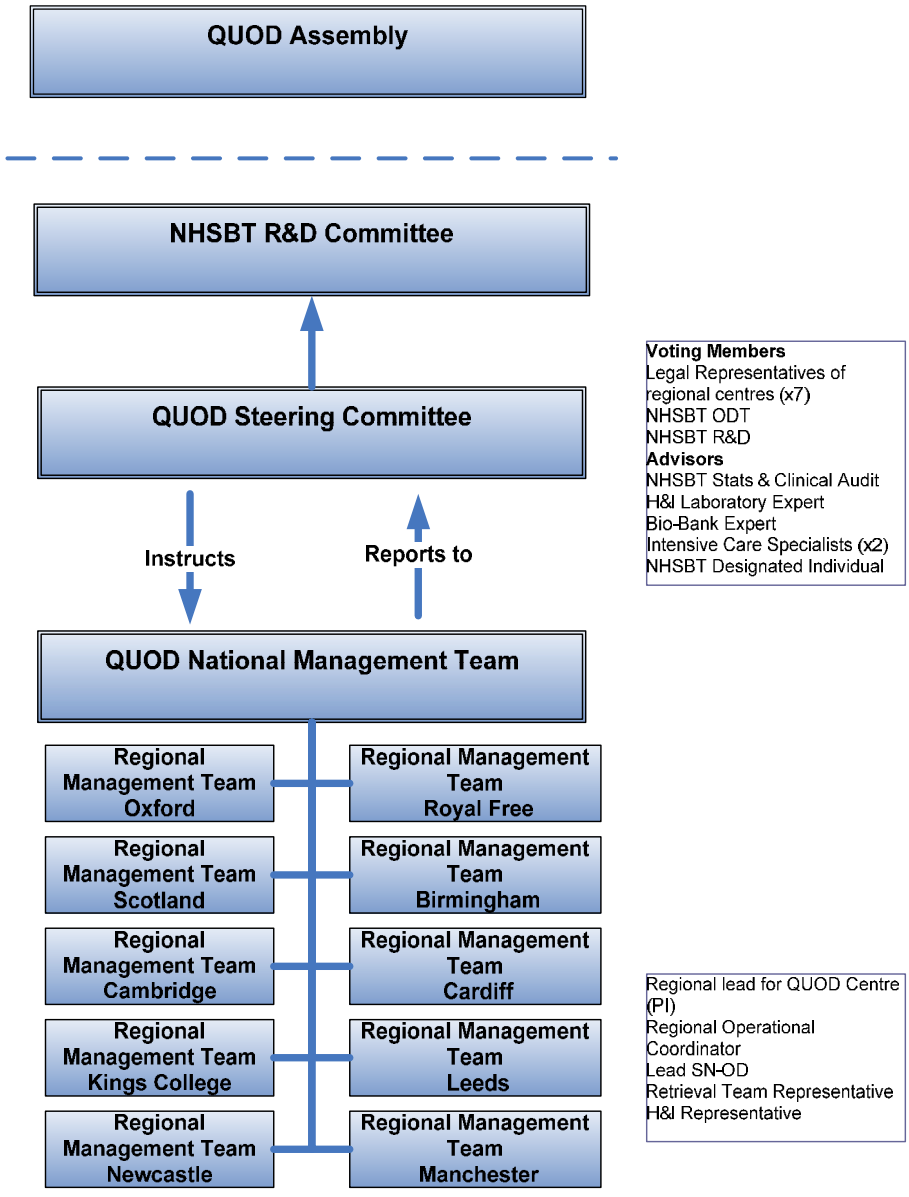


QUOD Incident Reporting & Management



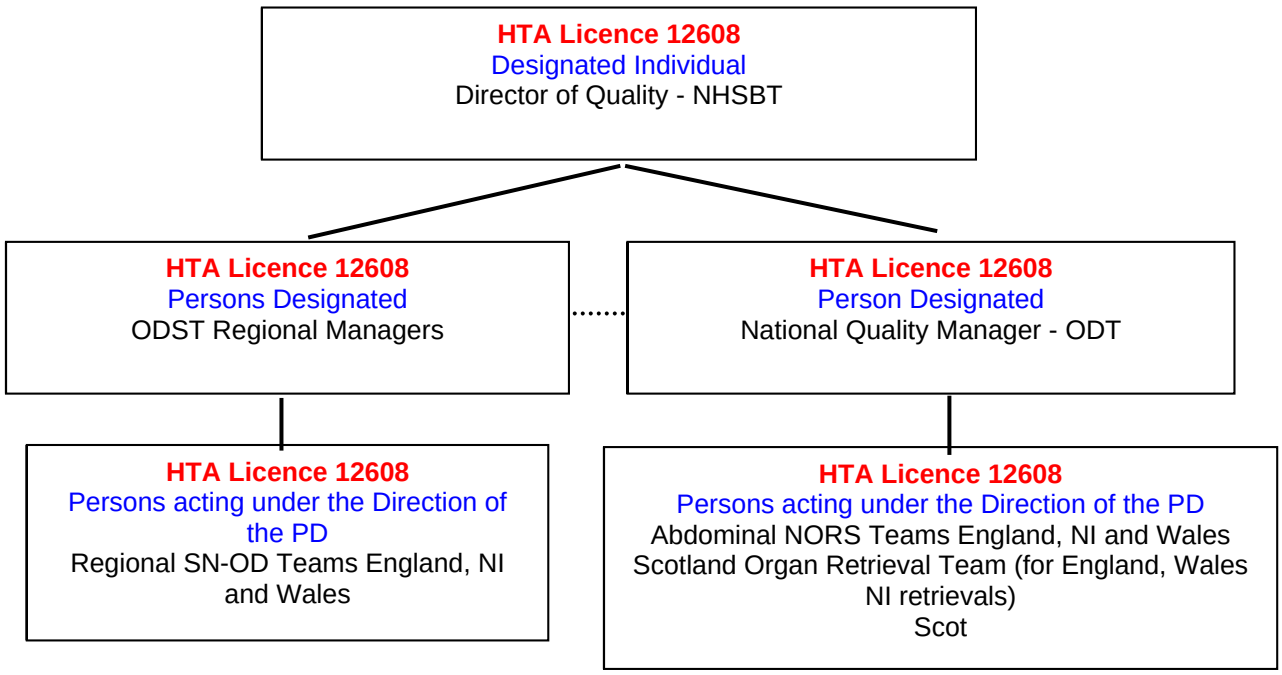
Appendix A – QUOD Governance

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.



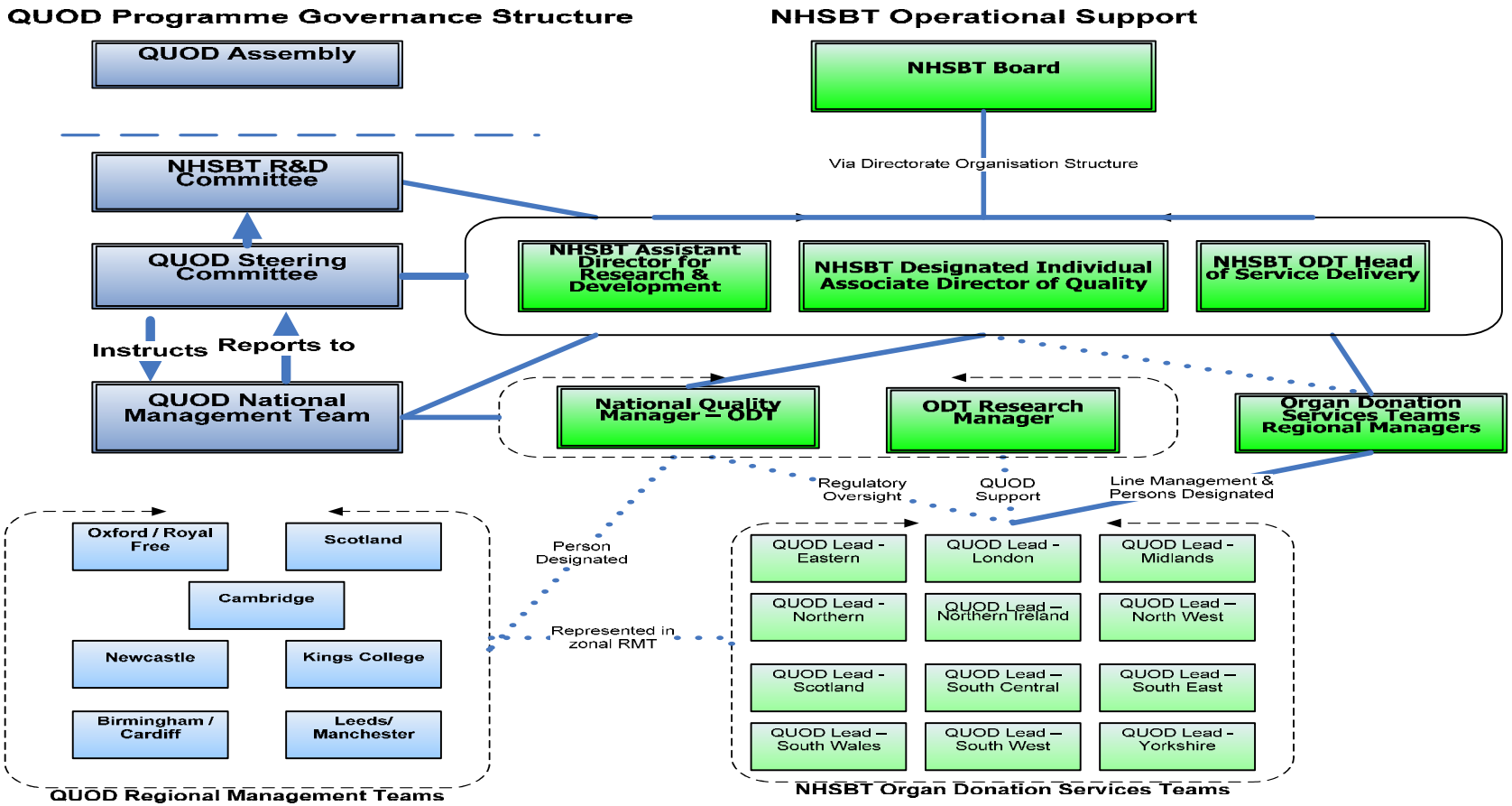
Appendix B – Designated Individual Supervisory Governance Structure

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.



Appendix F – Risk Scoring Matrix

The scoring matrix which has been used to assess each risk is shown below.

The risk score calculation = Impact x Likelihood.

		Likelihood				
		Rare 1	Unlikely 2	Possible 3	Likely 4	Almost Certain 5
Impact	Negligible 1	1	2	3	4	5
	Minor 2	2	4	6	8	10
	Moderate 3	3	6	9	12	15
	Major 4	4	8	12	16	20
	Catastrophic / Critical 5	5	10	15	20	25