

APPENDIX 5 – RESPONSIBILITIES

This section outlines the various stakeholders involved in the application process and their respective responsibilities. It provides a description of the different operational teams involved in organ donation and transplantation.

Title	Responsibility
AG Chairs	Members of RINTAG. Responsible for providing expert input into research applications.
Chair of RINTAG	Responsible for liaising with the Research Project Manager (RPM) to ensure all relevant research studies, service evaluations, novel technologies and other projects are reviewed appropriately by RINTAG, as described in this document.
Chief Investigator / Research Team	Responsible for liaising with the RPM regarding the relevant aspects outlined in this document; for ensuring all the regulatory and governance issues are addressed and evidenced appropriately; for adhering to any operational considerations deemed suitable by NHSBT. Provide periodic feedback/ updates on the research and at completion of the study to NHSBT and the SN-OD teams involved, where relevant ¹ .
NHSBT R&D Office	Responsible for issuing written confirmation of NHSBT operational support for study categories 5, 6 (and 7, where relevant). Providing support and advice to the RPM and SNRSD. Maintaining oversight of activity. Separately, responsible for NHSBT Sponsorship.
National Organ Retrieval Service (NORS).	<p><u>Function:</u> Comprises abdominal and cardiothoracic teams who attend organ donations to perform organ retrieval.</p> <p><u>Regional/ hospital:</u> Adheres to the agreed national NORS standards to provide a high standard of operative care and safety.</p> <p><u>Impact on research:</u> NORS teams will retrieve organs for transplantation which may subsequently be offered for research if deemed untransplantable². NORS teams should retrieve organs/ tissues solely for the purposes of research³ provided that:</p> <ol style="list-style-type: none"> i. They are already attending the donor. ii. They have been given reassurance that the local study is on the NHSBT registry of 'live' research programmes and the necessary consent is in place regarding the retrieval of the organ. iii. When mobilised, NORS teams will be notified about all organs required - including for research purposes. iv. That local licences and approvals are in place, where required. v. The team is competent to retrieve the required organ/ tissue. vi. The organ/ tissue falls within the normal NORS remit (e.g. NORS teams would not be required to pituitary glands) <p>The decision to retrieve for research purposes is thereby made at a national level. Organs placed for research should be retrieved after all organs accepted for clinical transplantation have been retrieved safely.</p> <p>For more complex studies, where research retrieval outside the normal NORS teams' remit and competency is proposed, further agreement and</p>

¹ A detailed account of responsibilities are outlined in the Letter of Agreement, available upon request

² Applicable to study category 4

³ Applicable to study category 5, 6 (and 7, where relevant)

	consultation is required as to who will perform the retrieval. The ODT Research Facilitation Team will be available to facilitate such discussions.
ODT Associate Medical Director	Responsible for providing the final approval sign-off from ODT for all supported research studies and to bring any relevant proposals to the attention of ODT CARE.
ODT Research Project Manager (RPM)	Coordinates and facilitates the ODT research approval process, liaising with prospective applicants and other relevant stakeholders throughout the entire process. First point of contact for all applications. Works closely in collaboration with the SNR and the Quality Assurance Manager.
ODT SMT	Final decision regarding the approval of relevant research studies. Has the right to veto any recommendations made by RINTAG. Responsible for reviewing appeals relating to RINTAG decisions.
Quality Assurance Manager	<u>Function:</u> Ensures Quality and safety for NHSBT and external stakeholders. <u>Regional/ hospital:</u> Maintains safety within organ donation and transplantation <u>Impact on research:</u> Oversees the implementation of research studies which require additional SNOD/ NORS input. Ensures research does not have a negative impact upon the donation/ transplantation process and that all research projects are managed through the quality assurance framework. Ensures regulatory adherence and supports the RPM and SNR with HTA licensing requirement and consent processes expertise prior to RINTAG submission.
Research, Innovation and Novel Technologies Advisory Group (RINTAG)	Overall responsibility to ensure the research meets the strategic needs of NHSBT; the impact research may have on organ donation, retrieval and transplantation; the potential operational impact, and relevance of the study in meeting organisational objectives; and considers the reputational risk to the organisation.
RINTAG Executive Members	Responsible for reviewing all relevant research proposals, and provide expert advice regarding the suitability of the request.
Specialist Nurse in Organ Donation (SNODs)	<u>Function:</u> Obtaining valid consent/ authorisation from the appropriate person under the relevant legislation (Human Tissue Act 2004 or Human Tissue (Scotland) Act 2006, whilst working within the NHSBT procedures for Consent/Authorisation. Recording the Consent/ Authorisation as detailed in the NHSBT Consent/ Authorisation procedures. Informing the researcher that Consent/ Authorisation has been given. <u>Regional/ hospital:</u> 12 regions of SNOD teams across the UK. Embedded within hospitals and also cover all other hospitals whilst on call. <u>Impact on research:</u> Ensuring any organ retrieved for transplant purposes and subsequently deemed unsuitable, after being offered to all the appropriate transplant centres, has being considered for research. Provides update to the NORS team during the handover in theatres, about any local research studies that has gained specific research consent for which the team has been asked to retrieve.
Clinical lead for organ donation	<u>Function:</u> Within the hospital Trust/ Board. Lead on promoting, supporting and advising clinical staff and SNODs

(CLODs)	<p><u>Regional/ hospital:</u> Each region has an overall clinical lead for organ donation to advice/ support and disseminates new information/ protocols as advised by NHSBT.</p> <p><u>Impact on research:</u> CLODs are to be informed of new research which will require any additional resources/ input at local hospitals.</p> <p>Complex studies may be discussed further at National Organ Donation Committee (NODC) for feedback for the research team.</p>
Specialist Nurse for Research and Service Delivery (SNR)	<p>Coordinates and facilitates operational considerations for ODT research projects, working closely with the ODT Research Project Manager, liaising with the applicant and other relevant stakeholders through the implementation phase. Provides SNODs with study-specific training on obtaining research Consent/ Authorisation.</p>