Retrieval Advisory Group

May 2025

Operational Governance for Service Development Proposals

Background

There is a well-established process for applications to access support and resources for research projects. Forms are completed by the research requester, and the applications discussed/signed off at the Research Operational Feasibility Group (ROFG).

There is currently no formal process or operational oversight to manage either those service developments that sit between research and the commissioned service, or brand new service development proposals which are agreed at the ROFG (eg Uncontrolled DCD, uterine transplantation).

Historically, this has been managed by the Commissioning and Service Development Team as part of a bigger programme of work, such as the DCD Heart programme or development of the ANRP service. However, as machine perfusion technology advances, more centres wish to explore use of these technologies. As such, there is a requirement to introduce robust operational governance. Improved operational oversight will help address any issues arising from service developments, ensuring ongoing support can be provided and any learning captured. This pooling of knowledge and expertise as a result of centralised oversight can in turn be shared with centres onboarding new technology.

Issues with Current Process

Some NORS and transplant centres have approached NHSBT via the Transplant Development, or Commissioning and Service Development team. When this happens, the process can be managed by setting up a change control, and direction can be provided about what is in and out of scope for operational delivery and funding.

However, as technology expands and new techniques are developed, centres are starting to explore service developments without always engaging with NHSBT at the outset, which leads to several issues:

- Lack of clarity about in/out of scope transport journeys, consumables and workforce payments, leading to disputes
- Teams mobilising with new/different equipment without undertaking field trials with the transport provider
- Lack of engagement with Hub Operations, leading to delays, challenges over mobilisation decisions
- Change Controls/Risk Assessments not being routinely undertaken for new developments
- OTDT Senior Management Team not being sighted on any impacts to commissioned service

New Process

The outline process is as follows – note that the proposal is to trial this for six months, and there may be occasions where Stages Two and Three are switched around (so the CC/RIA

takes place after authorisation by SMT) if this is a brand new development and/or there is likely to be an impact on the commissioned services.

STAGE ONE - REQUESTING

- Tell us early so we can advise and support, ensuring your processes align with our pathways and processes
- Complete the Service Development Request Form
- The Transplant, Service Development and Commissioning Team (TSDC) will allocate a reference number

Following review of the form, the TSDC team will notify the requester of dates/times when the team is available for discussion

Capacity will be carved out on a fortnightly basis to avoid delays.

As part of these calls, support will be available from the TSDC team to complete the form and provide guidance on any gaps/areas for clarification

STAGE TWO – CHANGE CONTROL

Following completion of the form, if there is capacity amongst the TSDC team and the relevant lead nurse/s, a Change Control will be opened. Principle that we refer to previous CCs if these exist, rather than starting afresh each time.

Requester to nominate a lead with contact details to work with OTDT on the Change Control/Risk Assessment and to liaise with regarding ongoing actions for completion and any operational and other issues arising in Stage Four.

Stakeholders:
Information Governance
QA
Patient Safety
OTDT Hub Operations
ODSTs
Finance
Transport Provider

STAGE THREE - AUTHORISATION

When the form has been completed and all relevant information provided, update to go to SMT for information/approvals. The TSDG will make recommendations to SMT regarding next steps including governance.

STAGE FOUR – IMPLEMENTATION AND MONITORING

Internal review of progress via the Commissioning Team monthly meetings, including an oversight of all incidents related to the change, actions/changes arising, any queries or concerns raised by the Requester and outcomes from any routine reviews/debriefs.

TO ESTABLISH CLARITY AS PART OF THE PILOT: how do we build in operational oversight of projects established via ROFG? Can we obtain clarity on the process of sighting SMT on issues (clinical/operational) that arise as a result of research/SDs?

Requesters must sign up to the principle that services may be suspended in the event of a clinical incident, until a formal debrief can take place and actions assigned to prevent recurrence/share learning.

Potential stakeholders who may need to be involved:
Richard Baker/Patient Safety
AMD/National Clinical Lead Organ Retrieval
QA
Transport Provider
IT
Statistics and Clinical Studies

APPENDIX A – DRAFT SERVICE DEVELOPMENT APPLICATION FORM

FRM xxxx NHSBT Service Development Project Application Form

If you application is regarding Research please visit https://www.odt.nhs.uk/odt-structures-and-standards/research/apply-for-research-approval/ and complete FRM – 4624 – NHSBT ODT Research Application Form If you are unsure if your application is research please visit https://www.hra-decisiontools.org.uk/research/ to access the NHS Health Research Authority decision tool.	
Title of Service Development Project	
Summary Service Development Project	
Service Development Project Applicant:	Title and name:
	Email address:
Proposed project start date	
Estimated end of Service Development Project	
Governance – to be completed by the applicant	
Hospital Trust/ Board approvals in place	*Please specify and attach evidence as required*
Hospital Trust/ Board approvals in progress	*Please specify and attach evidence as required*
How does this proposal meet the aims of the NHSBT Strategy	*Please specify and attach evidence as required*
Clinical Protocol	• Completed *(please attach)* ☐ • In development ☐ • Not started yet ☐
Funding	• Received ☐ • Sought ☐ • Not applied for ☐ • Not applicable ☐
TO BE COMPLETED BY THE TSDC:	
Impact on Existing Operational Processes	*Transport:* *Will the proposal involve movement of team/organ/equipment?* *Has a field trial been undertaken with IMT?* *Power source requirements in van/on plane?* *Check in/out of scope requirements in NORS Contract (we can create a shareable document for applicants)* *Hub Operations:* *Is there an impact on current mobilisation processes?* *Impact on offering/allocation?* *Operations/Donor Hospital:* *Impact on consent/authorisation processes?*

Technical Specification	*CE Marking in place?* *Has altitude testing taken place?*
Consumables?	
Impact on NORS Team	*Will the on call NORS team be responsible for supporting this? Workforce payments required – if so, who is paying?* *If using NORS, clarify need for 24/7 availability for commissioned service* *Commissioned service takes priority*
Regulatory Requirements	*MHRA approval – is a waiver required? Is this in place?* *Is HTA involvement/guidance required?*

Please submit your completed application to (Generic email Service Development Project Application)

Please attach your completed protocol if available and evidence of Hospital Trust/Health Board approvals in place.

APPENDIX C – HIGH LEVEL PROCESS