Changes in this version

- References to the new routes by which organs will become available for scheduled/other purposes through the National Allocation Scheme, as a result of the **I**ncreasing the **N**umber of **O**rgans **A**vailable for **R**esearch (INOAR) project
- Terms and Definitions added
- Addition of Authorisation Restrictions section
- Updates to the scoring system, approved by RINTAG

Policy

This policy has been primarily created by the Research, Innovation and Novel Technologies Advisory Group (RINTAG), in collaboration with Hub Operations; the NHSBT R&D Office and; the Quality Assurance department, on behalf of NHSBT ODT.

The policy has received final approval from ODT CARE, which acts on behalf of the NHSBT Board, and which will be responsible for annual review of the guidance herein.

It has been developed in relation to the following controlled documents:

- ***MPD1468**: Research Study Manual - ODT*
- ***SOP4442***: *Allocation of Organs and Tissue for Research & Novel Technologies – Hub Operations*
- ***MPD871**: Research Governance*
- ***POL198**: Non Compliance with Selection and Allocation Policies*
- ***MPD565**: Guidelines for the use of Donated Material*

First drafted: October 2016

Definitions

- **HTA -** Human Tissue Authority. The HTA regulates and licenses the removal, storage and use of human tissue for a range of activities in England, Northern Ireland and Wales.
- **IRAS -** Integrated Research Application System. An online dataset for applying for research approvals.
- **National Allocation Scheme -** The process by which ODT Hub Operations offer and allocate untransplantable organs to studies for use in scheduled/other purposes.
- **NORS -** National Organ Retrieval Service. Surgical retrieval teams, commissioned by NHSBT, that retrieve organs for transplantation and scheduled/other purposes.
- **Other purposes - *Applicable in Scotland:*** purposes other than transplantation, requiring authorisation; education/training, audit, research.
- **Relevant Material -** Material that consists of or includes human cells (except gametes).
- **RINTAG -** Research, Innovation and Novel Technologies Advisory Group
- **Scheduled purposes - *Applicable in England, Northern Ireland and Wales:*** purposes other than transplantation, requiring consent; education/training relating to human health, clinical audit, research in connection with disorders or the functioning of the human body, quality assurance, performance assessment, public health monitoring.

1. Overview

Organs can be offered to RINTAG-approved studies through the National Allocation Scheme by the following routes:

1. They are retrieved from the organ donor with the intention to transplant them but are deemed to be untransplantable after they have been removed.

2. They are determined to be untransplantable before removal from the donor (i.e. there is a clinical contraindication to transplant, such as diabetes for pancreas donation)
3. They are deemed to be transplantable prior to retrieval and are offered for transplant, but are declined by all transplant centres before removal and therefore retrieved for the primary purpose of research.

In all three routes, there must be consent/authorisation from the organ donor's family for scheduled/other purposes.

Routes 2 and 3 both fall under the **I**ncreasing the **N**umber of **O**rgans **A**vailable for **R**esearch (INOAR) project.

At present, only hearts, lungs and diabetic pancreases are available by routes 2 and 3 (i.e. INOAR)

Additionally, in routes 2 and 3, removal of organs for scheduled/other purposes can only take place:

- In English, Welsh and Northern Irish hospitals covered by NHSBT's HTA licence (no. 12608). These are listed in **INF1081**.
- In all Scottish hospitals, where HTA licences are not required.

In route 1, organs will be offered after removal; this may be at the donor hospital, en route to another hospital or a NORS team base, or at a transplant centre.

In routes 2 and 3, organs will be offered through the Scheme before removal, and only removed if a study accepts the offer.

Studies receiving organs through the National Allocation Scheme are prioritised by RINTAG as part of the application process and given a rank. This document provides an overview of the prioritisation and National Allocation Scheme processes.

This policy will be subjected to an annual review.

Non-compliance to these guidelines will be handled directly by NHSBT, in accordance with the Non-Compliance with Selection and Allocation Policies ***POL198****.*

2. Allocation Policy Development

This policy has been developed in relation to **MPD871** which outlines research governance best practice. This is stipulated in the UK Policy Framework for Health and Social Care Research, applicable to all research undertaken by, or in, the Department of Health and Social Care, its non-departmental Public Bodies and the NHS. This includes clinical and non-clinical research in health and social care.

As stated in the Guidelines for the use of Donated Material (**MPD565**), NHSBT is responsible for ensuring that donated material which has been supplied to hospitals and which is still suitable for clinical use must not be used for any other purposes.

All projects involving organ donation, retrieval and transplantation, and supported by NHSBT and its employees must be approved by NHSBT ODT. This approval is delegated to the Research, Innovation and Novel Technologies Advisory Group (RINTAG).

2.1. RINTAG's aims

The aims of RINTAG are:

- to provide NHSBT and other stakeholders with an overview of current research;

- to support the implementation of appropriately approved and funded research, innovation and service development;
- to perform horizon scanning;
- to work with commissioners and others to ensure that the introduction of novel approaches improve the outcomes of patients undergoing solid organ transplantation, in line with NHSBT's strategies.

Further information about RINTAG can be found on the ODT Clinical Website.

3. Study Ranking

Studies receiving organs through the National Allocation Scheme are prioritised to ensure that organs are allocated to the studies likely to have the highest benefit on transplantation.

3.1. Study Prioritisation matrix

New studies that will receive organs through the National Allocation Scheme will be assessed according to the criteria below, and ranked against all existing studies:

Banding classification:

1. If successful will the research organ be transplanted?

Scoring criteria:

1. **Feasibility:** the number of research organs required per year, as a percentage of the organs that are offered in a year.
   NB. For studies that are already live, the number of organs they have already received is incorporated into this calculation.
2. **Study classification:** basic science related to transplantation, clinical study related to transplantation or unrelated to transplantation
3. **Peer-review**: was the study peer-reviewed, and if so by who?

Binary categories:

2. Does the study involve multiple transplant units and/or educational institutions working together?
3. Is the study aligned to OTDT's strategy?
4. Does the study aim to evaluate novel technology in organ transplantation?

3.2. Scoring approach

Studies with the intention to transplant offered research organs are given the highest priority. Thereafter, ranking will be made in line with the following assessment criteria;

- Highest score and highest number of binary categories (i.e. highest score in the prioritisation criteria and highest number of 'Yes' in the binary categories)
- In the event of an equal score the number of binary categories will determine the priority.
- In the event of an equal score and equal number of binary categories, priority will be given to the study with the highest scored categories. For example, Study 'X' and Study 'Y' have equal number of binary categories and both have a score of 18. Study X has 4 'A's and 1 'C'. Study Y has 3 'A's and 2 'B's. Therefore, Study X is ranked above Study Y.
- In the event that two scores are identical, the studies will be given equal ranking. In the event that both studies accept an offered organ, organs will be allocated on a geographical basis.

Re-scoring and re-ranking of all studies will be made to accommodate for changes. Researchers are required to provide regular progress reports to aid in monitoring and evaluation.

3.3. Ranking approach

The ranking exercise is a guide to RINTAG only and any outcome of the ranking procedure could be over-ruled by RINTAG if a compelling case is made to do so.

The ranking will be undertaken per organ type, where it is expected that approximately 2 – 10 studies will be prioritised against one another.

The ODT Research Team will undertake the ranking exercise. The outcome will then be forwarded on to RINTAG executive members for approval. Members with any conflict of interest (i.e. an interest in any of the studies being ranked) will be excluded from this approval process.

New studies are ranked as part of the RINTAG approval process. All studies are re-ranked following the return of progress reports. Once a re-ranking has been approved by RINTAG, all active studies will be notified. At all times the ranking of studies will be made available through the ODT Clinical website.

4. Offering procedure

ODT Hub Operations have access to the live ODT Research Registry in order to allocate organs for scheduled/other purposes.

Hub Operations send a simultaneous message to all researchers within the organ group being offered, providing them with the details of the available organ (e.g. location, organ, primary reason that it can't be transplanted).

Researchers must respond within 45 minutes if they wish to accept the organ. The organ will be allocated to the highest-ranking study that responds to the offer within the 45-minute deadline.

In the event of responses from two studies with exactly the same rank, the organ will be offered on a geographical basis.

Any research organs that have not been accepted by ranked studies are then offered to NHSBT ODT approved tissue/biobanks.

This process is described in more detail in **SOP4442**.

4.1. Research Restrictions

In accordance with the Human Tissue Authority's Code of Practice on Research, donor families should be provided with information to support the consent/authorisation process and given the option to withhold consent/authorisation for one or more of the following:

- Human tissue in animals
- Genetic testing
- Commercial sector (including fees for cost recovery)

This information is captured in the research information leaflet (**INF1167 / INF1235**) given to donor families. It is also built into the research allocation scheme to ensure donor family wishes are respected:

- The offer message includes any restrictions put in place by the donor family.
- It is expected that researchers will not respond to a message that contains restrictions applicable to their study
- Each study has its restrictions listed on the ODT Research Registry, which Hub Operations use to allocate organs to studies
- The organ will be allocated to the highest ranked study which has no applicable restrictions

4.2. Authorisation Restrictions

In addition to the research restrictions as outlined above, Scottish donor families can also restrict which other purposes their relative's organs are used in.

For example, a Scottish donor family could say 'yes' to the use of their loved one's organs in education/training, but 'no' to their use in research or audit.

As the allocation scheme is national, all studies receiving organs this way are asked to declare if they could be classed as education/training and audit as they are likely to receive offers from Scotland.

5. Monitoring impact

Researchers are asked to notify the ODT Research Team of any changes to their study; for example, if the number of participating centres increases so that it becomes a multi-centre study, or if the overall number of organs required changes.

Researchers are expected to provide progress reports as requested. These are used to assess performance and provide data for improvement and monitoring purposes, and to inform the re-scoring and re-ranking of all studies. The Statistics & Clinical Studies team also produce allocation reports to RINTAG.

This streamlined offering procedure shifts the responsibility onto the response of the researcher and thus ensures a more rapid offering process. A degree of self-selection when organs are offered remains, with the geographical issues of cold ischaemic times and transportation costs considered prior to responding to an offer.

Appendix 1 – Prioritisation matrix

Classification - Transplantation			
If successful will the research organ be transplanted?	Mark	Score	Definition
Yes	I	100	The study protocol demonstrates that the organ will be transplanted as part of the study unless there are clinical indications that it would not be safe to do so.
No	II	0	The organ will not be transplanted as part of the study.
Not applicable	III	0	The study is not related to organ transplantation.
Scoring Criterion 1 - Feasibility			
Feasibility - number of research organs required per year	Mark	Score	Definition
<25 % of available organs	A	4	At the time of the prioritisation process, the study will require 25% or less of the anticipated number of specific organ type.
26 - 50 % of available organs	B	3	At the time of the prioritisation process, the study will require between 26% - 50% of the anticipated number of specific organ type.
51 - 75 % of available organs	C	2	At the time of the prioritisation process, the study will require between 51% - 75% of the anticipated number of specific organ type.
76 - 100 % of available organs	D	1	At the time of the prioritisation process, the study will require between 76% - 100% or more of the anticipated number of specific organ type.
Scoring Criterion 2 - Clinical Implementation			
Closeness to Clinical Implementation	Mark	Score	Examples
Clinical Study Related to Transplantation	A	4	A study testing a perfusion machine or new surgical technique to improve transplantation. In IRAS, may be covered by the following categories: • Clinical trial of an investigational medicinal product • Clinical investigation or other study of a medical device • Combined trial of an investigational medicinal product and an investigational medical device • Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice • Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

Basic Science Study Related to Transplantation	B	3	A study using techniques such as 'omics' (e.g. genomics, proteomics, metabolomics) analysis or searching for biomarkers indicating transplantability. In IRAS, may be covered by the following categories: • Study limited to working with human tissue samples (or other human biological samples) and data (specific project only) • Basic science study involving procedures with human participants
Study Unrelated to Transplantation	C	1	The study, whether deemed clinical or basic science, is unrelated to transplantation.
Scoring Criterion 3 - Peer-reviewed			
Peer-reviewed study	Mark	Score	Definition
External peer review	A	4	The study has been peer-reviewed by an external, national organisation (e.g. NIHR)
Institutional peer review	B	3	The study has been peer-reviewed by a local body or one to which the researcher is affiliated (e.g. Trust R&D grant award; local charity)
Not peer reviewed	C	2	The study has not been through any peer-review process.
Binary Category 1 - Multiple Groups			
Multiple transplant units and/or educational institutions working together	Mark	Score	Definition
Yes	Yes	n/a	The study *does* involve two or more transplant units and/or educational institutions working together to deliver the study
No	No	n/a	The study does *not* involve two or more transplant units and/or educational institutions working together to deliver the study
Binary Category 2 – Strategy Alignment			
Is the study aligned to ODT Strategy?	Mark	Score	Definition
Yes	Yes	n/a	There is evidence that the study will either directly or indirectly support the delivery of the aims and/ or specific actions within ODT's Strategy.

No	No	n/a	There is no evidence that the study will support the delivery of ODT's Strategy.
Binary Category 3 - Novel Technology			
Evaluates novel technology in ODT	Mark	Score	Definition
Yes	Yes	n/a	The study *is* aiming to evaluate the use of novel technology in organ donation, retrieval and transplantation.
No	No	n/a	The study is *not* aiming to evaluate the use of novel technology in organ donation, retrieval and transplantation.