POLICY POL263/1

Allocation of Research Organs

This Policy replaces *NEW*	**Copy Number**
	Effective **DRAFT**

Summary of Significant Changes

N/A

Policy

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

The policy has received final approval from the Transplant Policy Review Committee (TPRC), 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[1]:

- *MPD1029/4 ODT Research Approval Process*
- *SOP4442 Allocation of Research Organs 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
Approved by TPRC: April 2017

Aim of policy

The aim of this document is to provide an overview of the research organ allocation policy, including the study prioritisation, ranking and offering of;

a. solid organs[2] from deceased donors whose death has been defined by brain-stem death criteria (DBD donors) or from deceased donors defined by circulatory death (DCD donors);
b. which have been deemed unsuitable for transplantation and declined by all centres[3];
c. gained appropriate research consent/ authorisation;
d. subsequently been made available for research;
e. allocated through the national research organ allocation scheme[4];
f. available to studies that have undergone the appropriate approval route, prioritisation and ranking[5];
g. and are thereby registered on NHSBT ODT's Research Registry[6].

[1] In addition, please see other vital documents in the reference list at the bottom of this document, also informing this POL
[2] Solid organs defined by the HTA as relevant material from deceased donors, outlined here.
[3] Herein referred to as *discarded organs*
[4] As described in this POL
[5] Please see section 2.1 for more details
[6] Please contact the ODT Research Project Manager, at ODTresearch@nhsbt.nhs.uk, for a copy of the most up to date version of the Research Registry

This policy applies to all proposed research studies in the UK where the applicant requests access to organ donors and/ or "relevant material"[7] from donors for research purposes. It does not include proposals looking to remove organs purely for the purposes of research following specific research consent/ authorisation[8].

This policy will be subjected to an annual review. Additional reviews and refinements may be undertaken, particularly following the first 6 months of the policy pilot launched 20th February 2017.

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

1. Allocation policy development

This policy has been developed in relation to the above mentioned controlled documents[9], of which *MPD871* outlines research governance best practice. This is stipulated in the Department of Health's Research Governance Framework for Health and Social Care (2nd Edition)[10], applicable to all research undertaken by, or in, the Department of Health, it's non-departmental Public Bodies and the NHS. This includes clinical and non-clinical research in health and social care.

1.2 The development of the Research Allocation Policy

As stated in the Guidelines for the use of Donated Material (MPD565), NHSBT is responsible to ensure 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. Each NHSBT Directorate has been tasked with establishing an approvals process for which it has the authority to approve requests for material. The process includes defining the types of requests which can be approved by the Directorate nominated individuals, managed by the NHSBT ODT Research Facilitation Team. The Research, Innovation and Novel Technologies Advisory Group (RINTAG[11]) will be responsible for making recommendations to ODT Senior Management Team.

1.1.1 RINTAG's evolution

The research allocation policy was developed following the establishment of the Research, Innovation and Novel Technologies Advisory Group (RINTAG). The group originally emerged from the Novel Technologies in Organ Transplantation (NTOT) Working Party as a result of the recommendations within the UK strategy; Taking Organ Transplantation to 2020. The final report from NTOT, which included the recommendation for NTOT to evolve into RINTAG, was agreed by Advisory Group Chairs, UK Commissioners, UK Health Departments and NHSBT in September 2014.

1.1.2. RINTAG's aims

The aims of RINTAG is to provide NHSBT and other stakeholders with an overview of current innovations and supporting the implementation of appropriately approved and funded research, innovations and service development, horizon scanning and working with commissioners and others to ensure the introduction of novel approaches to improve the outcomes of patients undergoing solid organ transplantation, in line with the UK Strategy 'Taking Organ Transplantation to 2020'.

[7] "Relevant material" from deceased donors refers to the definition set out by the HTA and encompasses solid organs, associated tissues and/ or biopsy samples, as outlined here.
[8] See section 2.1 for more details
[9] Please also refer to other vital documents informing this POL, in the reference list at the bottom of this document
[10] Replacement version in progress by the HRA
[11] Further described in section 1.1.1 – 1.1.3

RINTAG subsumed the role of NHSBT's Research Strategy Group in Organ Donation and Transplantation and the research section of ODT Care meetings. Having assumed these responsibilities, RINTAG brings together representatives of transplantation, research, development, operations, commissioning, governance, retrieval and finance[12].

Additionally, RINTAG considers changes to clinical care, scientific developments, the political landscape, and actions of competitors that impact on NHSBT's product or service provision.

1.1.3 RINTAG within the NHSBT R&D structure

The R&D Committee is responsible to the NHSBT Board for the conduct of NHSBT research. The Research Strategy Groups, one of which has been replaced with RINTAG, provide a forum where research staff and operational staff in each business unit can discuss research strategy, and how research might have an impact on day-to-day operations. RINTAG formally reports into ODT SMT, with close liaison with the NHSBT R&D Senior Management Team[13].

1.2 RINTAG's Allocation of Organs for Research Policy Sub-group

The first Sub-group established under RINTAG was the Allocation of Organs for Research Policy Group. It was chaired by NHSBT's Assistant Director - Research and Development. Membership included representatives from the NHSBT Hub Operations; CT and abdominal transplantation; research community; and NHSBT Transplant Development.

The Sub-Group's aim was to establish a priority system for research studies when demand outstrips supply, with the remit to review current NHSBT processes, policies and documents relating to the allocation of unused organs for research (research organs[14]), to:

- Identify any issues with the current NHSBT processes and policies and make recommendations on how these could be improved.
- Ensure that the process for applying to NHSBT to access research organs is clear, streamlined and aligned with best practice.
- Make recommendations regarding an allocation scheme for research organs.

The group reviewed current policies and documents for all stages of the research organ allocation process, from the submission of a request to access organs through to the processes for allocating unused organs for research purposes. A stakeholder consultation exercise was undertaken. Building on this work, the Sub-group made recommendations as outlined below, which were approved by RINTAG and ODT SMT and subsequently reviewed by ODT CARE and the TPRC.

2. Allocation policy

Research applications submitted to NHSBT ODT Research Facilitations Team will be subject to two review phases; *application screening* and *study prioritisation*.

2.1 Application screening

In the initial application phase, all proposals submitted to the NHSBT ODT Research Project Team will be screened according to the following study categories:

[12] Please see RINTAG's ToR for full details

[13] Please see *MPD871 Research Governance* for more details

[14] The subgroup specifically looked at organs retrieved for transplantation and subsequently deemed unsuitable for transplantation. Therefore, this overall policy excludes research studies which requires specific research consent/ authorisation for the removal of organs purely for the purposes of research

Category No.	Category title	Reference	Description
1	Data study	DS	Studies with a pure statistical focus, not requiring access to "relevant material" e.g. undertaking analysis of existing data on transplantation
2	Qualitative study	QS	Studies with a descriptive or behavioural focus, not requiring access to "relevant material" e.g. examining attitudes toward organ donation
3	Biological sample study	BS	Studies looking to access blood, urine and tissue samples from deceased organ donors. Facilitated via the national biobank resource Quality in Organ Donation (QUOD). Samples are collected at four different time points covering the donor management period, all the way through to the point of organ retrieval
4	Study on organs deemed untransplantable following removal from the donor	UR	Studies requesting access to solid organs by generic research consent/ authorisation[15] i.e. organs that are removed from the donor for the purpose of transplantation but are subsequently deemed unsuitable for transplantation. Organs are offered via the NHSBT Hub Operations to approved studies. RINTAG prioritises and ranks approved research studies.
5	Study on organs removed specifically for research	RR	Studies proposing to retrieve relevant material from donors, purely for research purposes and as such will require specific consent/ authorisation from donor families, in addition to normal consent/ authorisation to remove other organs for transplantation. Studies in England, Wales and NI require HTA licensing considerations, according to the Human Tissue Act 2004. Licenses are not required in Scotland[16].
6	Donor intervention study	DI	Studies looking to undertake interventions in DCD donors prior to death[17], and/ or interventions to DBD donors e.g. drug administration to facilitate organ preservation.
7	Other studies	O	Studies which *may* require access to "relevant material" and/ or donors and is expected to have an impact on the donation, retrieval, and/ or transplantation processes.

Studies which fall in category 4 (UR) - Study on organs deemed untransplantable following removal from the donor, and; category 7 (O) – Other, when applicable
- are subject to the research organ allocation scheme for which this policy is intended.

Studies in category 5-7 (RR, DI and O, where relevant) - Retrieving organs and accessing donors purely for research purposes - requires specific research consent/ authorisation and/or extended

[15] The Human Tissue Act 2004 (England, Wales and Northern Ireland) specifically uses the term *'consent'*, whilst The Human Tissue Act 2006 (Scotland) uses the term *'authorisation'*.
[16] Please find more details about the legislative requirements in Appendix 3.
[17] Studies looking to remove tissues from DCD donors pre asystole falls under the Mental Capacity Act 2005 and/ or the Mental Capacity Act (Northern Ireland) 2016

HTA licenses.[18] RINTAG will assess these studies according to their suitability, the overall estimated impact on donation, retrieval and transplantation processes, and any reputational risk. They will also be subject to operational impact and risk assessment. Studies in category 5-7 (where relevant) are excluded from this policy because they do not require organs to be allocated via the national research allocation scheme.

The NHSBT ODT Secretariat will liaise with the prospective applicant to ensure all necessary governance and operational aspects are considered. This includes ensuring requirements such as funding, REC, and other approvals are in place where needed. The reviewing stage will also consider operational impacts, such as assessing the proposed research processes; impact and risk to the donation process and; method of consent/ authorisation[19].

2.2 Study Prioritisation

The proposal will then be processed through a prioritisation matrix to ensure that available organs are allocated to those studies likely to have the highest benefit on transplantation[20].

2.2.1 Study prioritisation matrix

New studies subject to the prioritisation matrix (i.e. category 4) will be assessed according to the below , and later ranked against all existing studies[21]:

Banding classification:

I. If successful will the research organ be transplanted?

Scoring criteria:

1. Feasibility – number of research organs required per year
2. Time-scale from start of study to increase number of organs available for transplantation
3. Peer-reviewed study

Binary categories:

1. Does the study involve multiple transplant units and/or educational institutions working together?
2. Is the study aligned to Taking Transplantation to 2020?
3. Does the study aim to evaluate novel technology/ies in organ transplantation?

2.2.2 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 criterion 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 on a 6-monthly basis to accommodate for changes (such as criteria no. 2: Time-scale). Researchers are required to provide regular progress reports to aid in monitoring and evaluation.

[18] As per the HTA 2004 legislation applicable in England, Wales and Northern Ireland

[19] Please see MPD1029/4 and the *NHSBT ODT Research Application Handbook* for a more detailed account of the application process

[20] Please see section 2.2 for more details

[21] Please find the full table, including the assessment criteria, in Appendix 1

2.2.3 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 group, whereby currently it is expected that approximately 2 – 10 studies will be prioritised against one another - depending on organ type. The following organ groups will be considered:

- Hearts
- Lungs
- Livers
- Pancreas
- Kidneys
- Bowel

The ODT Research Project Team will undertake the ranking exercise. The outcome will then be forwarded on to RINTAG executive members[22] 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. The ranking exercise will be undertaken bi-monthly, to accommodate new studies. Once the ranking has been approved by RINTAG, all active studies will be notified of the revision and any implications this may have to their study. At all times the ranking of studies will be made available through the ODT website.

2.2.4 Offering procedure[23]

To ensure this information is readily available during the offering procedure, the Hub Operations will be provided with the updated Research Registry following the agreed revised ranking and will offer research organs according to this list.

The Hub Operations will send a joint SMS message to all relevant researchers, providing them with the details of available organ (e.g. location, organ condition). Researchers will be required to respond within 45 minutes if they wish to accept the organ. The organ will be allocated to the highest ranking study that responded to the offer within the 45-minute deadline.

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

Any research organs that have not been accepted by NHSBT ODT approved studies would be offered to NHSBT ODT approved tissue banks.

2.2.5 HTA Code of Practice

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

1) the commercial sector including cost recovery (tissue banks) and/ or;
2) genetic testing/ DNA analysis and/ or;
3) animal studies

[22] This group consists of clinical experts as well as NHSBT staff members. Please see RINTAG's ToR for more details
[23] For more details, please refer to *SOP4442 Allocation of Research Organs Hub Operations*

This information is captured in the research leaflet given to donor families. It is also built in to the research allocation scheme to ensure donor family wishes are guaranteed, as following:

- The Hub Operations will make offers to all studies in a given organ group, informing of any restrictions placed on the offer
- The additional filter will occur once the 45 min deadline has passed
- In cases when a family has opted-out from any of the above categories, offering responses from such studies will be omitted
- The organ will be offered to the next highest ranked study

3. Monitoring impact

Researchers are asked to notify the ODT Research Project Team of any changes that may impact on their ranking. 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 six-monthly progress reports. These will be used to assess performance and provide data for improvement and monitoring purposes, and to inform the six-monthly re-scoring and re-ranking of all studies.

This data will not only be used for ranking purposes but will also allow ODT to monitor the efficacy of the policy. The ODT Stats. & Audit Team will produce annual 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 ischemic times and transportation costs considered prior to responding to an offer.

While this is expected, the new policy will see a change from a largely geographical allocation of research organs, to a prioritised approach with individual research studies being prioritised by RINTAG according to the above mentioned criteria. This will ensure the scarce resource of research organs is being utilised in line with NHSBT ODT's strategies, priorities and resources.

4. References

1. *NHSBT ODT Research Application Handbook; Obtaining Support for Research Studies - Guidelines to Prospective Applicants*
2. *From efficacy to equity: Literature review of decision criteria for resource allocation and healthcare decision-making* Lalla Aïda Guindo1, Monika Wagner1, Rob Baltussen2, Donna Rindress1, Janine van Til3, Paul Kind4 and Mireille M Goetghebeur1,5* Guindo et al. Cost Effectiveness and Resource Allocation 2012, 10:9 http://www.resource-allocation.com/content/10/1/9
3. SMT Update RINTAG 2015 05 14 document
4. RINTAG – Organ Allocation Subgroup: Summary of Recommendations document
5. Taking Organ Transplantation to 2020
6. Sup-group member invitation letter
7. Final recommendations RINTAG Research Organ Allocation Sub-Group May 2016
8. Prioritisation matrix
9. RINTAG's ToR

Appendix 1 – Prioritisation matrix

Classification Transplantation			
If successful will the research organ be transplanted?	Mark	Score	Definition
Yes	I	n/a	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	n/a	The organ will not be transplanted as part of the study.
Not applicable	III	n/a	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 - Time-scale			
Time-scale from start of study to increase number of organs available for transplantation	Mark	Score	Definition
Within 18 months	A	4	It is estimated that the project will increase the number of organs available for transplant within an 18 month period from the start of the study. This includes either directly (e.g. through novel forms of organ preservation making previously unsuitable organs safe for transplantation) or directly (e.g. through reducing the risk of patients developing organ failure or extending graft survival rates).
19 - 36 months	B	3	It is estimated that the project will increase the number of organs available for transplant between 19 and 36 months from the start of the study
> 37 months	C	2	It is estimated that the project will increase the number of organs available for transplant after 37 months or more from the start of the study
Not applicable	D	1	The study is not intended to increase the number of organs available for transplantation either directly or indirectly.

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 2020			
Is the study aligned to Taking Transplantation to 2020?	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 *TOT2020.*
No	No	n/a	There is no evidence that the study will support the delivery of *TOT2020.*
Binary Category 3 - Novel Technology			
Evaluates novel technology/ies in organ transplantation	Mark	Score	Definition
Yes	Yes	n/a	The study *is* aiming to evaluate the use of novel technology/ies in organ donation/ retrieval/ transplantation.
No	No	n/a	The study is *not* aiming to evaluate the use of novel technology/ies in organ donation/ retrieval/ transplantation.