



**RINTAG**  
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**Title of Paper**  
Prioritisation of Lungs/ Study 59 following the introduction of INOAR

- 1. Status – Public**
- 2. Executive Summary**

In 2017 the NHS Blood and Transplant (NHSBT), Research Innovation and Novel Technologies Advisory Group (RINTAG), formed a sub-group to increase the number of organs available for research, the sub group was named INOAR.

INOAR proposals to increase the number of organs available for research were agreed in principle by RINTAG, Organ Donation and Transplantation SMT and Quality Assurance SMT in 2017.

As part of the implementation of INOAR it has been agreed that supporting research studies requiring specific consent / authorisation will become the exception. This decision has implications for Study 59, a study that requires specific consent for removal of organs in Northern Ireland.

This paper seeks to propose a recommendation that will enable Study 59 to continue be supported by NHSBT, ODT once INOAR goes live in 2018.

- 3. Action Requested**

Agree to the recommendation that once INOAR goes live, if potential donor families consent to the removal and storage of lungs for research or other scheduled purposes at the Royal Victoria, Belfast. Lungs are prioritised via the Allocation of Research Organs Policy to study 59, until 2021.

- 4. Background**

Organs from solid organs donors may be obtained for the purpose of research via two different routes;

- 1) 'Generic Research' – if organs are removed for the purpose of transplant and found not suitable – they can be used for research with appropriate consent / authorisation. Offered as per the Allocation of Research Organs Policy 263/1.

- 2) 'Specific Research' – organs can be removed for research if the appropriate consent / authorisation is in place – but premises need to be covered by a HTA licence for removal of relevant material for research (outside of Scotland) – Non NHSBT Centre-specific licenses have so far been used with the DI of that licence taking responsibility for the removal activity.

INOAR proposed that in order to increase the number of organs available for research, the NHSBT HTA licence could be utilised to allow for removal of relevant material (whole organs) in donor hospitals that currently hold satellite licences to permit removal of tissue samples for QUOD.

Potential donor families within QUOD hospitals (and all hospitals within Scotland) will be given to opportunity to consider the option to consent / provide authorisation for the removal of hearts, lungs and the diabetic pancreas for research. There are currently 41 QUOD hospitals in England, Wales and Northern Ireland, and XX hospitals in Scotland).

A retrospective review of proceeding donors at QUOD hospitals in 2017 – 2018 indicated that potentially 184 lungs may have been available for research (Appendix 1.)

## **5. Proposal**

NHSBT, ODT approved in 2015 a specific research study entitled 'Use of cadaveric human lungs from the UK by the ex-vivo lung perfusion research consortium', study 59.

From commencement of the specific research study 59 in February 2016 until February 2018, 13 lungs have been accepted for research study 59 and 10 lungs have been removed for research study 59.

On review of the Potential Donor Audit and Donor Path April 2017- March 2018. 4 lungs have been accepted for research study 59 and 3 lungs have been removed for research study 59.

Research study 59 is 1 of 3 organ specific research studies NHSBT, ODT currently support. The other 2 active organ specific research studies are research study, 58 and 66.

Research studies 58 and 66 also access organs via the 'generic' research route.

As part of the INOAR implementation it has been agreed that 'specific' research studies will become the exception. Reasons for this include low consent rates for organ specific studies and the lengthy and complicated process for specific studies to gain local DI support for HTA licence

requirements. The amount of time the ODT research team spend on the organ specific study application process can often exceed 280 hours.

Due to the predicted increase in hearts, lungs and diabetic pancreas that will become available via the generic research route, as a result of INOAR, the ODT research team have requested that study 59 access lungs for research via the generic research route once INOAR goes live.

Study 59 would cease to be an active specific research study as INOAR goes live (this would also apply to research studies 58 and 66).

As recognition of the positive working relationships between the Northern Ireland, Organ Donation Services Team, Study 59 and NHSBT, ODT it is proposed that until 2021, lungs at the Belfast Victoria Hospital are allocated to study 59, regardless of ranking.

The request for such an arrangement is also reflective of the geographical location of NI and the potentially prohibitive transport costs associated with transporting organs for research to NI from mainland UK.

Should study 59, wish to accept lungs available for generic research from QUOD hospitals or transplant centres other than the Belfast Victoria Hospital, they would be allocated as per the Allocation of Research Organs Policy, and responsible for the transport costs as per policy.

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