

**National Retrieval Group**

24<sup>th</sup> April 2019

**Increasing the Number of Organs Available for Research (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.

The main proposal of INOAR was to extend the existing Liverpool Research HTA Licence (12068) to permit the removal of whole organs for research purposes. This licence currently used for QUOD, covers 41 hospitals (England, Wales and Northern Ireland).

INOAR estimated that the new approach would result in an increased number of organs being available for research purposes (n=694).

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.

The INOAR project will be introduced in 2 phases:

- Phase 1 Removal of Heart, Lungs and Diabetic Pancreas for research
- Phase 2 Removal of whole organs for research

*The INOAR project includes the opportunities for the removal of organs for research in Scotland with appropriate authorisation, however for the purposes of this paper the process under the HTA Liverpool Research HTA Licence (12068) will be referred to.*

**3. Action Requested**

- Note the progress of the INOAR project, phase 1 implementation
- Support the removal of organs for research with the appropriate licensing and consent in place on INOAR project completion

**4. Background**

Utilising the Liverpool Research HTA Licence to remove organs for research will in addition to increasing the number of organs available for research, deliver the following benefits:

- Reduce the complexities of the consent process for families
- Reduce the complexities of the consent process for SNODS

- Enable a more consistent and transparent research allocation system
- Lessen the complexities for researchers by reducing the requirement for specific HTA licences

The INOAR project has encountered both Information Technology (IT) operational challenges and the initial go live date of November 2018 was not achieved.

Project management support has been in place since March 2019 to progress INOAR project.

## 5. Proposal

The end to end process for the INOAR donation and retrieval process is documented in Appendix 1 & 2.

Key information relevant for NORS:

### Consent

Families will be given to opportunity in QUOD hospitals to consent to the removal of whole organs for research purposes in the event of organs being contraindicated to organ donation for the purposed of transplantation or offered and declined by all centres for transplantation.

Families will continue to be asked with regards to their wishes in cases whereby an organ is removed for the purposes of transplantation and subsequently deemed unsuitable for transplantation.

Phase 1 of INOAR implementation will include the Heart, Lung & Diabetic Pancreas, the consent form has been updated to reflect these changes alongside electronic changes in progress to NTxD, EOS and Donor Path.

### Offering and allocation

Heart, Lungs and the Diabetic Pancreas will be offered to researchers using the current ODT research allocation sharing scheme. Offering and allocation will take place after the offering of organs for transplantation has been completed, at the same time as NORS teams are mobilised.

Researchers will have 45 minutes to respond to offers of organs for research and only organs accepted for research will be removed by NORS.

Removal of an organ for research will always be undertaken by a certified NORS team, who are fully cognisant of regulatory frameworks, and the knowledge of the relevant paperwork required.

NORS team members will only be requested to remove organs that they are certified to do so.

	Heart	Lung	Diabetic Pancreas
Abdominal NORS	Yes	No	Yes
Cardiothoracic NORS	Yes	Yes	No

Organs will be removed, perfused and packaged to exactly the same standards as organs removed for transplantation.

Clinical priorities will always take precedence.

Researchers will be responsible for arrange transport to collect an organ removed for research, payment of transport and timely return of organ transport boxes.

HTA A & B Research forms have been devised to ensure traceability

The number of organs removed for research purposes under NHSBT licence will be collated and provided to the HTA on an annual basis.

## **6. Next Steps**

NRG to be kept informed of progress with regards to INOAR implementation

NORS standards to be reviewed and updated to ensure the details with regards to organs retrieved for transplantation are captured.

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