



RINTAG
7th May 2019

Increasing the Number of Organs Available for Research (INOAR)

1. Status – Public

2. Executive Summary

2.1 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.

2.2 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).

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

2.4 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.

2.5 The INOAR project will be introduced in 2 phases:

- Phase 1 Removal of Heart, Lungs and Diabetic Pancreas for research
- Phase 2 Removal of all organ for research

2.6 *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

4. Background

4.1 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

4.2 The INOAR project has encountered software/ electronic and operational challenges and the initial go live date of November 2018 was not achieved.

4.3 Project management support has been in place since March 2019 to progress INOAR project. Weekly project team telecoms commenced in April 2019. Progress next steps, risks and issues are discussed via ODT Change Programme Board (CPB) monthly.

5. Update

Key information relevant for RINTAG:

5.1 INOAR Project Team

Work streams have been identified to progress key deliverables planned:

Theme 1	Documents
Theme 2	Training
Theme 3	Communications
Theme 4	Software/ electronic changes
Theme 5	Aligning with Consent/Authorisation Form changes and ODT Tissues regulatory requirements
Theme 6	Process Sign-Off
Theme 7	Pilot Test Go/No Go Checklist Go Live

A 'mini' planning review day will be held to further develop the current schedule of deliverables to identify an accurate Go Live date.

5.2 Software/ electronic changes

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.

In development:

Core Donor Data Form changes: The CDDF is still not in UAT; there is a certificate issue preventing the team from starting testing. No date or an estimate of when it will be in UAT (update 30/04/19).

13330 Removal of Research Organ codes: No release date to a number of dependencies (update 30/04/19).

Awaiting development:

15709 Removal of Research Organ codes: Research Organ codes to record when organs are removed solely for the purpose of research, then either transplanted or discarded. Research Organ codes to record when organs are retrieved for transplantation, then used for research and either transplanted or discarded. This feature will be considered for development July – September 2019.

5.3 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.

5.4 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.

5.5 Removal of an organ for research

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.

5.6 Governance and Traceability

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**

6.1 Continue to report progress of INOAR Project via ODT CPB (monthly).

6.2 Ensure effective stakeholder communications internal and external with regards to INOAR project development and delivery.

Author

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