INOAR FAQs

1. What is INOAR?

INOAR stands for ***I****ncreasing the* ***N****umber of* ***O****rgans* ***A****vailable for* ***R****esearch*. INOAR was a short-term sub-group of RINTAG (the Research, Innovation and Novel Technologies Advisory Group) which was tasked with exploring opportunities to increase the number of organs available for research.

The proposal that the sub-group recommended was approved by the ODT and QA Senior Management Teams (SMTs), and this is what's being implemented.
Here is a link to a short animation video explaining further about INOAR:https://app.vyond.com/videos/da64a444-63ec-491e-aa1d-bc6424cedac2

2. Why do we want to increase the number of organs available for research?

NHSBT is committed to improving and advancing healthcare, including transplantation. Increasing the number of organs available for research will, in turn, increase the number of organs available for transplantation. This occurs directly, by rejuvenating untransplantable organs so that they can be transplanted, or indirectly, by increasing our knowledge of transplantation medicine.

3. Which organs are in scope for INOAR?

Phase 1 of INOAR is limited to the removal of hearts, lungs and diabetic pancreases in selected hospitals. Organs will only be removed for research if they have been accepted by a research study prior to theatre.

It is envisaged that once Phase 1 of INOAR is implemented and there has been time to evaluate the process, Phase 2 will be implemented. Phase 2 will enable the removal of all organ types for research if they cannot be transplanted.

4. Why are we starting with hearts, lungs and diabetic pancreases?

Hearts, lungs and diabetic pancreases are currently difficult for researchers to obtain via the National Research Allocation Scheme because:

- Hearts and lungs are often declined for transplantation on offering, or prior to cross-clamp and retrieval for transplantation. In these situations, they currently cannot be removed for research.
- Diabetic pancreases are contraindicated for transplantation. As these organs are not retrieved for transplantation (and then declined), they are currently not made available for research.
- Hearts that are unsuitable for whole organ transplantation are preferentially used for tissues (e.g. valves and patches) instead of research

Removing hearts, lungs and diabetic pancreases for research allows researchers to access these vital organs and tissues that aren't frequently available through the National Research Allocation Scheme.

Organ Type	Number Offered Through the National Research Allocation Scheme in a 12-Month Period (Pre-INOAR)
LUNGS	21
HEARTS	2
DIABETIC PANCREASES	0
KIDNEYS	320
LIVERS	189
NON-DIABETIC PANCREASES	152

Starting with the three rarest research organs also allows us to implement INOAR in stages, ensuring that the process works for all of the teams involved before we consider rolling it out to the other organs.

5. Are the Human Tissue Authority (HTA) content with the proposed changes?

Approval is not required from the HTA but the INOAR project has been fully discussed with the HTA.

6. Do the organs need to be removed under an HTA licence? How will this work?

Yes; organs will be removed for research under the NHSBT research HTA licence (12608) in England, Wales and Northern Ireland. Removal of organs for research can take place within any hospital listed as a satellite of this licence (as for QUOD). Please remember all NORS team members carrying out removal of organs for research must be up to date with their HTA e learning (currently required for QUOD). The HTA e-learning weblink and module instructions are given in the Appendix at the end.

7. What happens in Scotland?

Scotland has different legislation and studies do not require an HTA licence to remove organs and tissues for research. As with QUOD, removal of organs for *other purposes* can happen at any hospital in Scotland.

8. Which donors are in scope for INOAR?

Only adults over the age of 16 years (Scotland) or over 18 years (rest of UK) are in scope.

9. How will the family consent/authorisation conversation take place?

Families will be given the option to consent/authorise the removal of organs for *scheduled purposes/other purposes*. The discussion for this will take place only after consent/authorisation for organ donation has been given**.**

10. Should the SNOD inform the Coroner/Procurator Fiscal about the removal of organs for research?

If the patient is being referred to the Coroner/Procurator Fiscal, the removal of organs for research must be included in the request.
Removal of relevant material or parts of the body (HTA/ Scotland) from a donor who requires referral to the Coroner/Procurator Fiscal, must not happen before discussions with the Coroner/ Procurator Fiscal .

11. What takes priority – organs for transplant or research?

Retrieval of organs for transplant will always take priority over removal of organs for research.

This also includes retrieval of the whole heart for tissue such as heart valves. Organs will be offered for transplantation first (if not contraindicated). Un - transplantable hearts, lungs and diabetic pancreases will then be offered for research if there is appropriate family consent/authorisation and a NORS team that is trained to remove the organ, is attending.

12. Will organs be removed for research only, if no other organs are placed for transplantation?

No; NORS teams will **not** be mobilised purely for research retrieval. The process will be stood down.

13. Where should the SNOD document consent/authorisation for removal of organs for research?

Consent/Authorisation Form: Document in question 3a of Section 5 (Consent Form) or Section 6 (Authorisation Form). Question 3a is new and includes specific boxes to record consent/authorisation for the removal of the heart, lungs and diabetic pancreas.

14. How will research organs be offered?

If there is consent/authorisation for the removal of organs for research, Hub Operations will send a pager to the relevant research studies with the offer of an untransplantable organ. The researchers have 45 minutes to respond to the offer if they wish to accept the organ. The organ will be allocated to the responding research study which has been ranked highest by RINTAG.
There are 2 time points when Hub Operations may offer organs to researchers:

1. Prior to theatre, when the organs are contraindicated for transplant, or have been offered for transplant and declined by all centres.

2. When organs have been retrieved for transplantation but have been found to be unsuitable on further examination on the back bench in theatre, or at the transplanting centre.

15. What happens if organs are declined on visualisation in theatre prior to retrieval? Will Hub Operations offer these out for research?

No; ODT Hub Operations do not currently have the capacity to do this.

16. Will INOAR delay the start of the donation operation?

No; the research offer will be sent simultaneously with NORS mobilisation. As the NORS teams routinely carry all the consumables required for the removal of organs for research, they can mobilise prior to organs being accepted for research.
The removal of organs for research will be discussed during the SNOD to NORS handover prior to theatre. This will not delay the start of the operation.

17. Can any NORS team remove the heart, lungs and diabetic pancreas for research?

No; NORS teams can only remove organs that are within their normal scope of practice:

Team(s) Mobilised	Can this organ be offered/removed for research?		
	Heart	**Lung**	**Diabetic Pancreas**
Abdominal and Cardiothoracic NORS	Yes	Yes	Yes
Cardiothoracic NORS only	Yes	Yes	No
Abdominal NORS only	Yes	No	Yes

NB. *Only hearts removed by a Cardiothoracic NORS team will be perfused*
Therefore, if no cardiothoracic team attends or the cardiothoracic team has to leave, the lungs will not be removed, and any interested lung studies will be stood down.

18. Are organs removed for research packed and perfused in the same way as organs retrieved for transplant?

Yes; organs will be packed with the same paperwork as organs retrieved for transplant. Most organs will be perfused by the NORS team. The only time this does not happen is when the heart is removed by the abdominal NORS team. This is because perfusing cardiothoracic organs is outside of their normal scope of practice.

NORS Team	Can the Team remove this organ for research?		
	Heart	**Lung**	**Diabetic Pancreas**
ABDOMINAL	Yes (unperfused)	No	Yes
CARDIOTHORACIC	Yes (perfused)	Yes (perfused)	No

19. Who is responsible for packing the organs?

The Organ Preservation Practitioner is responsible for packing organs removed for research.

20. Who will be organising transport of research organs?

The researcher will arrange for the organs to be picked up while organs are collected for transplant. If there is any anticipated delay, then the research organ will be transported with the NORS team to their base to safely await collection.

21. What happens if the research study is unable to accept the organ from a different destination than the donor hospital (if the NORS team leaves the donor hospital with the organ and the researcher's transport hasn't arrived yet)?

The organ will be offered out again to all the appropriate research studies and/or research tissue banks. If no study or tissue/biobanks can accept the organ, it will be disposed of, but this should be very rare.

22. Does the retrieval surgeon need to document removal of organs for research?

Yes; removal should be documented on the HTA-A Research Forms (**FRM6296** for pancreases and **FRM6297** for cardiothoracic organs), in the hospital notes and on a witness 9 form if it has been requested by the Coroner, the researchers will be responsible for completing an HTA B form. If the organ is removed is not used for research as intended and the NORS team are required to dispose of the organ, a HTA B form will need to be completed by the NORS team.

Appendix; The Human Tissue Act Basics e-learning module

Completion of this e-learning is mandatory for compliance with QUOD and research organ removal. Please complete this module if you have not done so this year.

Access :

Step 1: Log on to https://nhsbt.traineasy.com/

Step 2: Click on the Login tab and enter a username and password using the details below. (If you get an error message saying 'User not available' this may be because the generic login is in use by another user, please try log in number 2 or 3).

1) Username: Persons.Designate01@nhsbt.nhs.uk / Password: PDTesting123

2) Username: Persons.Designate02@nhsbt.nhs.uk / Password: PDTesting123

3) Username: Persons.Designate03@nhsbt.nhs.uk / Password: PDTesting123

Step 3: Go to tab 'courses' and select; Training Catalogue / Mandatory Training / Role Specific / then open 'HTA – Persons Designated Training Module 1 – The Human Tissue Act basics'.

Step 4: Please complete this module and e-mail to confirm completion using the link in the module.