



FAQs for NHS sites

These FAQ's have been written by the research team involved in the United Kingdom Register of Stored Ovarian or Testicular Tissue (UKSTORE), to help answer any questions that NHS sites who are involved in UKSTORE may have. If your question isn't answered below, please get in touch with a member of the research team via:

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You can also find out more about UKSTORE via our website:

<https://ukfertilityregister.org.uk/>

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1. Who is leading the UKSTORE register and what expertise do you have?

UKSTORE is a collaboration between the University of Leeds, Oxford University Hospitals and the University of Edinburgh. It is run by a team at the University of Leeds, led by Professor Adam Glaser, a senior clinician specialising in children's cancer and long-term follow-up, and supported by experts in fertility, epidemiology and data governance. UKSTORE is overseen by an independent Steering Group and operates within the University's secure data environment.

2. Why is UKSTORE important?

Thousands of children and young people have had ovarian or testicular tissue stored to protect their future fertility, but nobody has ever been able to see the full picture of how they are doing long-term. UKSTORE is the first national register to collect this information across the whole UK population.

This helps us:

- Understand how well fertility tissue preservation works
- Improve safety and efficacy
- Improve NHS services and identify inequalities
- Ensure children and young people receive the best possible care

3. Who has approved this work?

Several national bodies have approved and overseen UKSTORE:

- Research Ethics Committee (REC) granted a favourable ethical opinion for the database
- Health Research Authority (HRA) & Confidentiality Advisory Group (CAG) approved the use of identifiable patient information without consent under Section 251 of the NHS Act 2006
- Information governance teams at the University of Leeds oversee data custody and security.
- HTA/HFEA were consulted and have confirmed their regulatory frameworks do not restrict this work.

4. How can you collect patient data without written informed consent from patients?

The HRA's Confidentiality Advisory Group (CAG) has given legal permission (known as *Section 251 support*) to allow NHS centres to share specific information with UKSTORE without asking every patient individually. This is allowed when:

- the work is clearly in the public interest
- asking for consent is not practical (e.g. many patients treated as children are now adults and no longer in follow-up)
- the team demonstrates strong safeguards

5. What if patients don't want their information to be included?

People who have already stored ovarian or testicular tissue in an NHS centre in the UK will be sent information about how their data is being used. This information will also explain how they can opt out if they don't want to be included. For people who store tissue in the future, information will be given about UKSTORE at the time the tissue is stored. You can find information leaflets on our website:

<https://ukfertilityregister.org.uk/>

Anyone whose information has been put into the registry can opt out at any time. They can do this by telling the fertility tissue preservation clinician in your NHS centre, who will complete a short form and send it to UKSTORE.

Patients can request that:

- their data is not added to UKSTORE, or
- their data is removed from future updates, or

- specific elements of their data are not included.

Their choice will be respected without question. Opting out does not affect their clinical care, their stored tissue, or their future fertility options.

If someone opts out:

1. Their identifying details are flagged at the storage centre.
2. Their data is not provided to UKSTORE in subsequent uploads.
3. If already received, identifiable data are removed and no further linkage is performed.
4. Only fully anonymised data already incorporated into statistical analyses may remain (as is standard practice), because this is no longer traceable back to a person.

No clinician or researcher sees identifiable data once an opt-out is recorded.

6. Has this way of collecting information been done before?

Yes. UKSTORE collects data in the same way as other national NHS registries, including the [UK cancer registries](#), [PICANet](#), and many [NHS datasets](#).

UKSTORE is supported by Section 251 support, which allows essential health data to be used for research and audit without individual consent when:

- it is in the public interest
- it is impossible or impractical to obtain consent from every person
- robust safeguards are in place
- patients have a clear right to opt out

7. Is it legal?

Yes. The legal basis comes from Section 251 of the NHS Act 2006, which allows confidential information to be used without consent for approved medical research when it is in the public interest.

- Approval letters from the HRA/CAG explicitly state that UKSTORE has permission to receive and process this information lawfully

- All other laws (e.g. GDPR, Data Protection Act) still apply, and UKSTORE is fully compliant.

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8. Is it ethical?

Yes. The Research Ethics Committee reviewed the protocol and confirmed that UKSTORE meets national ethical standards and is being run responsibly and transparently.

The ethics review considered:

- the sensitivity of the data
- potential risks and safeguards
- patient involvement
- opt-out processes

9. What do patients and parents think?

We held consultations with young people and parents who have stored tissue. Their feedback was clear:

- they support a national register
- they prefer an opt-out model rather than being asked for consent during stressful treatment
- they want whole-population data to improve future care

Quotes from the patient and parent engagement groups include:

“Absolutely vital that this information is linked to other datasets.”

“I feel more reassured that data is collected for learning and understanding.”

10. What does the Human Tissue Authority (HTA) say?

The HTA regulates how ovarian and testicular tissue is stored. UKSTORE does not store tissue itself; it only collects information. Storage centres already have HTA licences, and UKSTORE works within that framework. This aligns with HTA expectations laid out in the national advice forms and approvals in the registry site documents.

11. What does the Human Fertilisation and Embryology Authority (HFEA) say?

The HFEA confirmed that UKSTORE does not require HFEA approval, because it does not collect gametes or manage IVF-related procedures.

12. What does NICE say?

The establishment of a national database of quality-assured data on fertility tissue preservation was recommended by the National Institute Clinical Excellence (NICE) in 2023. Further details of their recommendation can be found here: [National Institute for Health and Care Excellence \(2023\) Removal, preservation and re-implantation of ovarian tissue for restoring fertility after gonadotoxic treatment \(Interventional Procedures Guidance IPG772\)](#)

13. What support will we get for preparing and sending data to UKSTORE?

UKSTORE provides:

- a clear protocol
- defined datasets
- a Withdrawal/Opt-out form for patients
- information sheets for families
- administrative support from the UKSTORE team
- a named investigator at each centre
- secure upload routes to the data storage location

14. How will this benefit our centre?

Centres gain:

- access to centre-specific audit and benchmarking and research data
- evidence to support service planning
- improved understanding of patient characteristics and outcomes
- national visibility of fertility tissue preservation activity
- support for quality improvement and commissioning conversations

15. How will this benefit patients?

Patients benefit because UKSTORE helps:

- improve and standardise care across the UK
- make sure the right children are offered fertility tissue storage
- identify inequalities in who gets access
- understand long-term outcomes (including future fertility)
- reduce unnecessary or ineffective procedures

This will help ensure safer, more informed care for children and young people.

16. How will the data be kept safe?

Data is stored in the Leeds Analytic Secure Environment for Research, which uses a high-security, cloud-based system with strict access controls, audit trails, encryption and backup procedures. Only a small number of trained staff can access identifiable data for essential tasks.

All releases to researchers use anonymised or pseudonymised data.

17. What will happen to the data if UKSTORE is no longer funded?

If funding stops:

- the University of Leeds remains the Data Controller
- data would be archived securely
- no new data would be collected
- existing anonymised data may still be used for research if appropriate ethical and legal permissions remain in place

This ensures that the value of historical data is preserved for the public benefit, even if the register closes.