

# Information for Participants

## Who is responsible for your data?

The joint data controllers for HERO trial are the sponsor organisation, Bradford Teaching Hospitals NHS Foundation Trust (BTHFT) and the University of Leeds (UoL). This means that both organisations are responsible for how your data is collected, stored, shared and used.

## What information do we collect about you?

Staff within the NHS collect information from you and your medical records for this research and send it to the Clinical Trials Research Unit (CTRU) at the University of Leeds. The CTRU will use your name, address, and contact details to contact you about the research study, namely for the purpose of sending questionnaires and providing any study updates.

Your NHS number, gender, initials, date of birth and postcode will be shared with NHS Digital, to obtain information about you from your electronic health care records. We will do this because it is a more efficient way to collect certain data about your health. By using data routinely collected from hospital/health visits, we can reduce the burden (such as the number of researcher contacts) on you and your hospital. When we do this linking, we will only use the data mentioned above to identify you, and we will follow strict rules when working with other organisations to maintain confidentiality and to protect your data. You can read more about NHS Digital here: <https://digital.nhs.uk/about-nhs-digital>.

The information received from NHS Digital and that from NHS staff will be entered into a database held securely at the Clinical Trials Research Unit. Individuals from the BTHFT (the study sponsor) and regulatory

organisations may look at your medical and research records to make sure the study has been run correctly. The only people at BTHFT and UoL who will have access to information that identifies you are the people involved in study follow-up (e.g., posting questionnaires) or auditing the data. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

## How long we keep your data

Bradford Teaching Hospitals NHS Foundation Trust and the University of Leeds will keep your data for a minimum period of 10 years after the end of the study, after which it will be securely destroyed.

## How we protect your data

We protect your personal data against unauthorised access, unlawful use, accidental loss, corruption or destruction.

We use technical measures such as encryption and password protection to protect your data and the systems they are held in. We also use operational measures to protect the data, for example by limiting the number of people who have access to the databases in which your data is held and using unique reference numbers to identify participants rather than names wherever possible.

We keep these security measures under review and refer to Bradford Teaching Hospitals NHS Foundation Trust and the University of Leeds Information Security Policies to keep up to date with current best practice.

## Sharing your data

Your personal data collected and managed by the University of Leeds will be used to carry out the follow-up of this trial, including linking your personal data with data held by NHS Digital. In order to do this, we will provide your initials, gender, date of birth, NHS number and postcode to NHS Digital. The information we have about you will be linked with the information held by NHS Digital. This will be done in a secure and confidential manner.

It is possible that the information collected about you might be shared with other research teams to answer new research questions in the future. If this happened, the information would be anonymised so that no-one would be able to identify you from it.

## Your Rights

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information:

<https://www.hra.nhs.uk/information-about-patients/>

<https://www.bradfordhospitals.nhs.uk/privacy-statement/>

<https://ctru.leeds.ac.uk/privacy/>

## Our legal basis to process your data

Organisations processing personal data need a legal basis for that processing activity. For public authorities, such as the NHS and

Universities, the most appropriate lawful bases when processing personal data and health data (defined as special category data) for the purposes of research are:

Article 6:1(e): Specific task in the 'public interest' or task that has a clear basis in law, and

Article 9:2(j): Special category data used for "Archiving in the public interest, scientific or historical research or statistical purposes", with a basis in law.

To ensure we carry out the research to the highest standards we comply with the UK Policy Framework for Health and Social Care Research. You can learn more about research standards here:

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>

## Complaints

If you wish to raise a complaint on how we have handled your personal data, you can contact the Data Protection Officer who will investigate the matter.

University of Leeds Data Protection Officer

- Phone +44 (0) 113 2431751
- Email: [dpo@leeds.ac.uk](mailto:dpo@leeds.ac.uk)

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO) by visiting <https://ico.org.uk/make-a-complaint/> or by calling their helpline on 0303 123 1113.