

Transfusion Requirements in Younger Patients Undergoing Cardiac Surgery (TRiCS IV)

Information you need to know:

Leicester Clinical Trials Unit is the UK coordinating centre for the TRiCS IV study and is part of the University of Leicester's College of Life Sciences (CLS).

The information in this privacy notice is intended to supplement specific information provided to research participants, for example, through participant information sheets or consent forms, with regard to their participation in research studies carried out by the University of Leicester.

This privacy notice explains how we use your personal information and your rights regarding that information.

What information are we collecting?

The identifiable information we will collect, if you give consent, is your NHS number, date of birth, gender and ethnicity. These will be used for the ONS data linkage as described in the Patient Information Sheet.

Why are we collecting your data?

A similar study called TRiCS III was recently completed. Your personal data will be used to support the existing data from the TRiCS III study. This study included about 5,000 patients over the age of 18 undergoing heart surgery using the heart-lung machine, comparing the restrictive transfusion strategy to the liberal transfusion strategy. The results of this study showed that the restrictive transfusion strategy was favoured in elderly patients, but we don't know yet which transfusion strategy is best for younger patients.

All participants taking part in the TRiCS IV study will help to make a significant contribution to research, as the results of this study will help determine when a transfusion is required for future patients having heart surgery.

For the purposes of the TRiCS IV study:

- St Michael's Hospital, Unity Health Toronto, Canada, will act as the Data Controller for the information entered onto the clinical trials database;
- The University of Leicester will act as the Data Controller for:
 - the data collected as part of the health economics and quality of life questionnaires;

the data collected as part of routine data linkage in the UK, in joint status with the Office for National Statistics (ONS).

For specific details of what information about why we are collecting your information, please refer to the Patient Information Sheet.

What is the legal basis for processing the data?

The legal basis for the processing of participant information that we are collecting and using for the study is Public Task as set out in the Data Protection Act 2018 and GDPR Article 6.1(e). Research is a public task that the University of Leicester performs in the public interest, and is part of its core functions as a University.

Where special category data will be collected, our additional conditions for processing information relies on;

Article 9.2(i); and that it is necessary for 'scientific research or statistical purposes' as set out in the Data Protection Act 2018 and GDPR Article 9.2(j).

If we are sharing your data with others, who are we sharing it with?

We will not share any personal data with third parties. Your information will be accessed by the research team at your local hospital. However, research information tends to be pseudonymised or anonymised; this means all identifiers such as NHS number, name, data of birth etc., are stripped from the records. This is normal practice and usually happens before we share the data or publish research outcomes.

Information collected during the TRiCS IV will be entered onto a secure database, with each enrolled participant allocated a unique ID so that the information remains pseudonymous. For more details, please refer to the Patient Information Sheet

Relevant sections of your medical notes and/or research data may be looked at by individuals from the research and clinical team, the Sponsor, University of Leicester, regulatory authorities or other NHS host organisations where it is relevant to your taking part in the TRiCS IV study.

If you would like to have further details about how your personal data is shared, please contact the research team of the study in which you are a participant.

How long will we process your data for?

Personal identifiable data collected during the TRiCS IV study will be kept by each participating site for a maximum of 12 months following the end of the study, after which it will be destroyed. All other paper and electronic data will be retained for at least 7 years after completion of the study, in accordance with the relevant standard operating procedures. Data will be stored at a University of Leicester approved archiving facility which will ensure that it is stored securely and accessed only by authorised individuals.

You will be able to find more specific information about the retention period in the participant information sheet the research team provided when you joined the study in which you are a participant.

What are your rights and how to enforce them?

As a research participant you have the following individual rights under Data Protection legislation:

- Access your personal information only applicable when identifiable data is still being processed – right to access
- Correct any inaccurate information – right to rectification
- Restrict or object to our processing of your information – right to restriction

However, please note that some of these rights may be restricted if the exercise of these may seriously impair research outcomes or after your information is pseudonymised

It is also important to understand that these rights will only apply if the research project holds identifiable information about you. Where your information has been completely anonymised, this information is no longer accessible and is therefore not classed as personal data for the purposes of the Data Protection Legislation. Therefore, the rights specified above apply will no longer apply.

How do I complain to the Information Commissioner's Office?

If you feel the research team in which you are a participant has not handled your personal data appropriately or have any concerns about your personal data, you can complain to the Compliance and Privacy Office, details below.

Unity Health Toronto Privacy Office
Unity Health Toronto c/o St. Michael's Hospital
30 Bond St.
Toronto
Ontario
M5B 1W8
Canada
Email: privacy@unityhealth.to

Data Protection Officer
University of Leicester
University Road
Leicester
LE1 7RH
Email: dpo@leicester.ac.uk

Also, you may complain to the Information Commissioner's Office, commonly known as ICO.

The ICO can be contacted via:

- Information Commissioners Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK95AF
- **Telephone:** 0303 123 1113
- **Website:** <https://ico.org.uk/>