Data Protection (GDPR)
UK Privacy Notice

Randomised comparison of the clinical Outcome of single versus Multiple Arterial grafts: The ROMA trial

Information you need to know:

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

The CLS conducts research activity which has obtained appropriate ethical and legal approvals. Data collected as part of our research activity is processed and stored strictly in the public interest. The College is able to assure compliance by following the UK Policy Framework for Health and Social Care Research.

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.

Please note that Weill Cornell Medicine/New York-Presbyterian Hospital is the Data Controller (i.e. determines why and how personal data is processed) for the information collected about you in the ROMA trial.

What information are we collecting?

The type of personal information and the purpose for which is collected will depend on the specific research objectives of the research activity. The detailed information about data collected will be or has already been provided to you through the participant information sheet before you agreed to take part in the ROMA trial.

We may collect information about you directly from you or on some occasions we may collect from third parties such as GPs or hospitals, when you have provided consent. The information collected will be proportionate to achieve the research objectives and our researchers will not collect more information than is actually needed.

Why are we collecting your data?

Your personal data will be used to support the existing observational data and all participants taking part in this trial will help to make a significant contribution to research into coronary artery disease, which may improve treatment for patients in the future.

The ROMA trial is a consortium of leading cardiology researchers and clinicians from across the world, working together to investigate the effect of single vs multiple arterial grafts in patients undergoing a coronary artery bypass graft (CABG).

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 trial 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?

Your information will be accessed by the research team at the 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 ROMA trial will be entered onto a secure password-protected database which will be provided and managed by Weill Cornell Medicine/NewYork-Presbyterian Hospital in the USA. Each enrolled participant will also be allocated a unique participant ID so that the data on the database remains pseudonymous.

Weill Cornell Medicine/NewYork-Presbyterian Hospital will also manage a research repository which is a collection of information from the health and medical records of trial participants and can sometimes include identifiable information (like date of birth). The repository includes codes that identify each person whose information is collected. However, the repository does not share information with researchers unless the researchers agree to keep the information confidential. In the consent form, you will be asked to indicate whether Weill Cornell Medicine/NewYork-Presbyterian Hospital can keep your protected health information for a research repository.

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

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

How long will we process your data for?

Personal data collected for research purposes tends to vary according to the purpose of the specific activity. However, health/medical research data tends to be long term use and storage.

Personal identifiable data collected during the ROMA trial 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, unless you have expressed an interest in receiving a copy of the trial results. All other paper and electronic data will be retained for at least 6 years after completion of the trial, in accordance with the University of Leicester and Leicester Clinical Trials Unit's standard operating procedures. The 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 or consent form the research team provided when you joined the trial 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 – 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.

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.

Compliance and Privacy Office - Weill Cornell Medicine
1300 York Avenue, Box 303
New York
NY 10065
USA
Telephone: (646) 962-6930
Email: privacy@med.cornell.edu

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

The Information Commissioner can be contacted:

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