

Information you need to know

Leicester Clinical Trials Unit is the central co-ordinating centre for the COLO-PREVENT trial and is part of the University of Leicester. Further information on the institution can be found here: <https://le.ac.uk/lctu> The University of Leicester is the Data Controller for your information.

The Data Protection Officer is: Elisabeth Taoudi, Data Protection Officer and Commercial Lawyer, University Of Leicester, University Road, Leicester, LE1 7RH. Tel: 0116 229 7640. Email: et177@leicester.ac.uk. This privacy notice explains how we use your personal information and your rights regarding that information

What information are we collecting?

- NHS number
- Initials
- Date of birth
- Gender
- Ethnicity
- Demographics and medical history
- Health information (medical records, blood pressure, ECG, medications)
- Questionnaire data (FFQ)
- Optional consent: full name and contact details

Why are we collecting your data?

We are doing this research to determine if drugs or food supplements could reduce the occurrence of bowel polyps, which in turn will reduce bowel cancer risk. This type of treatment is called 'therapeutic prevention'. In the main trial of the COLO-PREVENT research study we are looking at whether taking aspirin, or aspirin combined with metformin is better at preventing bowel polyps from re-growing.

How will we use this data?

All trial documentation containing identifiable patient data will be managed in accordance with ICH GCP, the UK Policy Framework for Health and Social Care, the Data Protection Act and the EU General Data Protection Regulation (GDPR).

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?

Information will only be obtained from the participant if necessary for the trial. The site research team will use the participant's name, NHS number and contact details, to contact them about participating in the trial and to make sure that relevant information about the trial is recorded, to ensure patient care and for quality assurance purposes. Individuals from the Sponsor, the LCTU, and regulatory organisations may look at participants' medical and research records to check the accuracy of the research trial but the identifiable data will not leave the site. The only people in the Sponsor organisation and LCTU who will have access to identifiable information will be those requiring it for trial purposes or for audit of the data collection process. The trial statistician only involved in analysis will not have access to identifiable information.

How long will we process your data for?

The trial team will keep participant contact information for 10 years after the trial has finished where participants have consented to being contacted about future research. Consent forms and details of record linkage (i.e., trial ID numbers/pseudonyms) will be archived for 25 years as part of the research data so that in the event of the data being challenged, this will allow for verification of the quality of the data.

Explicit (optional) consent will be sought to store identifiable contact details in order to invite participants to take part in future research. Participant name and contact details will be stored on a separate secure database by the University of Leicester (and its clinical trials unit, the Leicester Clinical Trials Unit) for up to 10 years after the end of this trial.

What are your rights and how to you enforce them?

You have the right to:

- Right to withdraw consent
- Right to be informed
- Right of access
- Right of rectification
- Right to erasure
- Right to restrict processing
- Right to data portability
- Right to object
- Rights related to automated decision-making including processing

How can you complain to the Information Commissioner's Office (ICO)?

The Information Commissioner's Office can be contacted via:

Post:

Information Commissioners Office
Wycliffe House
Water Lane

University of Leicester privacy notice

Wilmslow
Cheshire
SK9 5AF

Telephone: 0303 123 1113

Email contact can be made by accessing www.ico.org.uk