Will I be told the results of the study? Individual results will not be fed back, however, published study specific results may be available through the public access Exeter CRF website (Exeter Clinical Research Facility // Publications (exetercrfnihr.org))

Thank you for considering the information in this leaflet. If you wish to donate samples you will be asked to agree to the statements below in the presence of a member of our staff. A parent/guardian may provide consent for children under 16. A consultee may be asked to make a declaration on behalf of adults without capacity to consent for themselves.

1. I confirm that I have had opportunity to consider the information provided, ask questions and have had these questions answered satisfactorily.
2. I agree to donate samples and data available to the RD&E Tissue Bank and give permission for RDETB staff to obtain information from my medical records (including electronic) now and in the future.
3. I understand that my samples and hospital data will be stored securely at the Royal Devon & Exeter Tissue Bank in Exeter.
4. I understand that genetic material may be extracted from my samples and used for future research into the causes of disease.
5. I understand that my agreement is voluntary and that I am free to withdraw consent to use my samples and associated data at any time without giving any reason and without my medical care or legal rights being affected.
6. I understand that with the agreement of a Steering Committee the tissue bank will provide my anonymised data and samples to researchers, including those in companies, for the purpose of understanding disease and improving healthcare.

Optional Statements: I give permission for researchers to:-

1. feedback information to my referring hospital doctor that might be relevant to a) my current condition b) other conditions c) conditions that might affect my blood relatives. My clinician will decide whether further tests are needed on the basis of this information and may invite me for further consultations.
2. Contact me to provide me information about future research. I understand I am under no obligation to consent to take part in that research.

How can I find out more information? This project is managed by NIHR Exeter Clinical Research Facility under the direction of Consultant Physician Prof. Michael Gibbons. It is supported by the National Institute for Health Research, which is part of the NHS.
For independent advice about participation in research contact RD&E Patient Advice and Liaison Service on 01392 402093. For further information about the Tissue Bank please email us (rde-tr.tissuebanks@nhs.net) or call us on 01392 408178. If you would like to discuss your specific donation further with a clinician please contact: Dr Tariq Ahmad on tariq.ahmad1@nhs.net

This tissue bank has been approved by Yorkshire and the Humber, Leeds East Research Ethics committee. 21/YH/0159 IRAS 302472

NIHR | Exeter Clinical Research Facility

NHS Royal Devon University Healthcare NHS Foundation Trust

Royal Devon and Exeter Tissue Bank (RDETB)
The Exeter Gastroenterology Collection

Will you help us to improve healthcare by by donating medical samples for research?

- We are inviting you to donate samples or tissues (e.g. urine. blood, fat, biopsies) that are being taken either during your routine hospital care, a simple research study visit or a visit specifically to collect these samples.
- Some of the samples would normally be destroyed, but these and potentially extra samples could, along with information from your medical records, be used to help understand more about disease, and hopefully help improve treatment in the future.
- Your personal details will be removed and replaced with a code number before any samples and clinical information are shared with researchers.
- Everything is held securely within the RDETB
- We will ask if we may contact you in the future about further research but this is entirely voluntary and declining the invitation will not affect your future care.

The NIHR Exeter Clinical Research Facility is a partnership between the University of Exeter and Royal Devon University Healthcare NHS Foundation Trust. This project is supported by the National Institute for Health Research (NIHR) Exeter Clinical Research Facility. The views expressed are those of the author (s) and not necessarily those of the NIHR or the Department of Health and Social Care.

What is the purpose of the RDETB? RDETB helps doctors and scientists to understand more about the causes and progression of diseases, by collecting, storing and distributing spare or extra samples and body tissues obtained from people attending Royal Devon & Exeter Hospital or other NHS organisations working with the RD&E, for another simple research study or making a special visit to gift samples .





What will happen to my samples and data?
Samples will be kept in conditions to make sure that they are of use for future research. Routinely collected data, stored in your hospital records (including electronic records) will also be recorded. All information will be given a code which marries together sample, consent form and medical data and will then be stored securely in the RD&E Tissue Bank. RDETB staff may review your medical records in the future for additional clinical information, only these staff can link samples and data to you as an individual. Genetic material (DNA) may be extracted from your samples and used in research to understand the causes of disease. Coded data and samples (without your name) will be provided to researchers upon the approval of a Steering Committee made up of professional and lay people. The committee makes sure that samples are only used for well-designed, ethically appropriate studies aiming to improve understanding, treatment and diagnosis of human medical conditions.
Samples are often collected for use in local research however they may be provided anonymously to researchers elsewhere in the UK and abroad including academic organisations and commercial companies.
Samples and data will:

- Not be sold for profit
- Not be used in research into termination of pregnancy or human cloning.

What are the risks and benefits of taking part? The clinician will explain any particular risks of the samples you are being asked to consent for. Having blood taken may, for example, cause some discomfort and/or bruising. Samples will either be taken as extra during an existing procedure, saved from routine disposal or collected just for research. Your clinician will not allow samples to be taken if they could cause risk to you or affect accurate diagnosis of your condition. Samples donation is unlikely to benefit you directly, but your donation may help doctors and scientists improve treatment and

What happens if researchers find something relevant to my clinical care?
Your samples may not be analysed immediately and there is no guarantee that researchers will find anything relevant to your clinical care. However it is possible that in the future, research uncovers information that might be clinically relevant to your health or that of your blood relatives. With your consent, we will provide the hospital doctor who referred you to the Tissue Bank with research results, so that they could make a decision about informing you of information relevant to your current condition, other conditions that might affect you or genetic conditions that might affect your family. You may change your mind about the feedback you wish to receive at any point.

Which samples would you like me to donate? There are three requests: We would like you to donate an extra blood sample of up to a maximum of 80 mls (~4½ tablespoons) which will be taken when you have your routine clinical bloods. We may also ask you to donate a stool and/or urine specimen for research. We also seek your permission to use for research any previous or future clinically taken blood or tissue which is no longer needed for your clinical diagnosis and/or treatment either now or in the future.
What will they be used for? Your samples will be analysed by researchers, including those from commercial companies, to help understand the cause of gut disease, to develop new tests to diagnose and monitor disease and help develop new treatments. This research will include studying your blood, and genetic code (DNA / RNA).
How long will you keep them? Samples will be used for specific projects. Each project will be individually approved by the tissue bank steering committee. Your samples will be stored for many years, as long as the tissue bank exists.

Do I have to take part? No. Participation is entirely voluntary. It is up to you to decide whether to become a donor. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This will not affect the standard of care you receive from the NHS.

How will we use information about you? We will need to use information from you. This information will include your:

- Initials
- NHS number
- Hospital ID number
- Name
- Contact details including postcode

People will use this information to do the research, review medical records or to check your records to make sure that the research is being done properly. 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.

We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used? You can find out more about how we use your information from:

- www.hra.nhs.uk/information-about-patients/
- a leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- contacting the RDETB team on rde-tr.tissuebanks@nhs.net
- or 01392 408178 .
- RD&E data protection team on rde-r.dataprotectionofficer@nhs.net