

Thank you for reading this leaflet. If you wish to participate in this study, you will be asked to agree to the consent statements below in the presence of a member of the research team.

CONSENT STATEMENTS

1. I confirm that I have read this information sheet. I have had opportunity to consider the information, ask questions and have had these questions answered satisfactorily. *You should not give consent until you are happy that you understand what the study involves.*
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.
3. I agree to take part in this study. *This means that you agree to complete the questionnaire and have body measurements taken, give a blood and urine sample.*
4. I understand that my GP will be informed by NIHR Exeter Clinical Research Facility if any research findings indicate that I require immediate clinical care. *This means that if any of the measurements we take are significantly higher than the normal range we will ask one of our doctors to look at all of your results. If they believe that you need further tests or treatment they will contact your GP. Your GP will then invite you to a consultation to discuss these findings.*
5. I consent to gift my samples to the Peninsula Research Bank for future medical research. *This means that your anonymised genetic, blood and urine samples will be stored indefinitely and will be used for any study (both within the UK and abroad) deemed appropriate by the Peninsula Research Bank Steering Committee but specifically a) not to be sold for profit b) not to be used in animal research c) not to be used in research into termination of pregnancy or reproductive cloning d) not to be screened for genes/markers predictive of rare disease (this means that we will not be able to tell that you will develop a disease based on the results of genetic testing) and e) not be shared with non-research organisations, such as the police.*
6. I give permission for researchers within the NIHR Exeter Clinical Research Facility to access my medical records and to be flagged on relevant healthcare databases. *This means that we can update the information about your medical history automatically and will know if you develop any diseases. Having stored blood samples from participants before they develop a disease is incredibly useful in helping us to understand how we can improve early diagnosis of these conditions. We will ensure that any medical information about you is handled with the strictest confidence.*
7. I give permission for my contact details to be kept on a secure database by the Peninsula Research Bank and to be contacted about other research in the future. *This means that we may contact you in the future if we have a specific research project that requires participants of your age, gender or medical history. You will be asked how often you are happy to be invited to future studies and we will not contact you more frequently than this. You are not obliged to participate in any further studies, but we would appreciate it if you will consent to be invited.*

Help us improve healthcare



through research

Everyone can help

What does joining Exeter 10000 involve?

Exeter 10000 is a research project that any adult can join.

Participation involves a 30 minute appointment including:

- Answering a short questionnaire about your health & lifestyle
- Providing a urine sample
- Blood pressure and body measurements (e.g. height, weight, hip/waist ratio)
- Providing approximately 50ml (2 tablespoons) of your blood
- You will be offered the opportunity to receive a copy of your health measures and blood tests. You may also choose to have these results copied to your doctor.

Find out more or make an appointment by
telephoning 01392 408181

Exeter 10000 – Volunteers for Medical Research.

We would like to invite you to be one of 10,000 people in the Exeter area to participate in our research volunteer bank. Before you decide, we would like you to understand why the research is being done and what it would involve for you. This information sheet will give you details of the study. If you wish to ask any further queries, one of our team would be happy to answer your questions.

Why are we doing this research?

Common diseases such as diabetes, heart disease and dementia are major health problems. The NIHR Exeter Clinical Research Facility has been set up to look closely at how common diseases develop, so that we may identify the best treatments, and see how we could prevent them happening in the future. Rather than taking a random approach, we want to focus questions on why some people are predisposed to disease and why some people are protected. Key to this approach is identifying and establishing a large group of individuals, with and without health problems, from whom we can collect and analyse blood samples and health information. They would also need to be willing to be approached in the future, if they were identified either genetically or from the other health information that they had provided, as being someone who could best help us to answer to a specific research question.

What will I need to do?

Appointments can be either fasting (nothing to eat or drink, except water for 10 hours) or non-fasting (eat and drink as normal). Fasting blood samples can provide more detailed information on blood glucose and cholesterol levels than non fasting samples, so can be used for a wider number of research questions. Fasting appointments will be offered in the earlier part of the morning, usually from 8.30 onwards. We will ask you not to eat or drink anything apart from water for ten hours before your appointment time. After your appointment we will provide you with breakfast and ensure you are comfortable before you leave us. Non fasting appointments will be offered from late morning onwards and we will ask you to eat and drink as normal before your appointment. People with diabetes will be offered a non fasting appointment as blood samples are already measured regularly as part of their routine care. All participants will be advised to drink plenty of water before their appointment to ensure they do not become dehydrated.

Do I have to take part in this study?

No. Participation is entirely voluntary. It is up to you to decide to join the study. If you agree to take part, we will ask you to sign a consent form like the one overleaf. You are free to withdraw at any point. Participation in the study will not affect your treatment as an NHS patient.

What will happen to my samples and data?

Once initial measures have been taken we will transfer your samples and data to the Peninsula Research Bank. This will ensure their safe use in the future. All samples will be given a unique code. All personal identifying information will be kept separate from your data and may only be accessed by the Peninsula Research Bank data management team. The Peninsula Research Bank steering committee will approve the use of samples for research into common disease, healthy ageing and other relevant medical research. This research may form part of collaborations in the UK or overseas including collaborations with scientists within companies. Genetic material (DNA and/or RNA) will be extracted from all samples and may be used in an anonymous fashion in studies examining the genetic basis of common diseases.

Specifically samples:

Will not be sold for profit

Will not be used in animal research

Will not be used in research into termination of pregnancy or reproductive cloning

Will not be screened for genes/markers predictive of rare diseases (e.g. Huntingdon's)

Will not be shared with non-research organisations, such as the police.

We will also contact you, as often as you deem appropriate, to invite you to take part in ethically approved future studies.

Are there any risks in taking part?

Blood samples will be taken by fully qualified personnel who are covered by NHS indemnity for negligent harm. Any potential discomfort or side-effects will be equivalent to that experienced giving a blood sample to your GP. As with any screening, GP visit or health check, the study could discover previously unknown health problems. Early diagnosis of these problems may allow them to be more effectively treated. However once identified they will form part of your medical record and so, may impact on future life or health insurance applications. The screening will not include tests for HIV or sexually transmitted diseases.

What will happen to the results of the research study?

Participants will be sent a newsletter informing them of results of studies which have made use of their data. Results will also be published on our website and in scientific journals. When published all data will be anonymous and no link will be made to any personal identifiers of participants.

Will my participation be kept confidential?

Yes. We will follow current ethical and legal practice, and all information about you will be handled in confidence.

Who is organising this research?

The research will be managed through the NIHR Exeter Clinical Research Facility which is funded by the National Institute of Health Research, a part of the NHS.