Participant Information Sheet (Bioresource version 2.0)

UK IBD Microbiome study

You are being invited to participate in the UK IBD (Inflammatory Bowel Disease) Microbiome study. Before you decide whether or not to do this, it is important for you to understand what the study is and what will be involved. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear or if you would like more information. Take plenty of time to decide whether or not you wish to take part. You can contact your BioResource directly or the clinical study team (contacts at the end of this sheet).

What is the purpose of the study?

Inflammatory bowel disease (IBD) is a disease of the digestive tract that affects 1 in 250 of the UK population. The two main types are Crohn's disease and ulcerative colitis. Despite major advances with medical therapy over the past twenty years, IBD remains incurable and an important cause of ill-health. Over the last decade, doctors and scientists have made significant progress in understanding the causes of Crohn's disease and ulcerative colitis, and we believe that these diseases may result from problems in the way the body's immune or defence system interacts with the bacteria that live in the bowel. This study aims to understand better the different types of bacteria that live in the bowels of people with and without inflammatory bowel disease. In particular, we hope to learn how the types of bacteria are influenced by differences in the genetic code of people who take part.

Why have I been asked to take part?

We are aiming to get stool samples from people whose genetic information is already available in a Bioresource such as the one in which you have participated. This will allow us to relate the information about the bacteria that we find in their stool to what we know about their genetic code.

What will this involve?

If you agree to take part, we would ask you to provide us with a stool sample and complete a short questionnaire about your general health, lifestyle and dietary habits. You will also need to provide informed consent. Collection of the stool sample and informed consent will be arranged directly by your Bioresource. They will provide you with a stool collection kit and details about collecting and transporting your stool sample. This is a very simple procedure that can be done from the comfort of your home. The whole process should take you no more than about half an hour.

Do I have to do this?

No, it is entirely up to you if you want to take part in this study. You can also change your mind at any time, without giving a reason. If you change your mind later on however, some of your samples may already have been used in research. It would be too late for us to stop your sample being used, but we would dispose of any of the sample that hadn't been used yet.

What are the possible benefits of taking part?

Nothing for you personally, but the results of the research carried out could possibly benefit the whole of society, or help the health of future generations of people.

What are the possible disadvantages or risks of taking part?

There are no identified risks associated with taking part in this study.

Where will my sample be used?

- The NHS
- Universities
- Research Institutions
- Commercial companies

Samples may also be sent abroad. You can be sure, however, that all researchers whether in this country or abroad must have proof that they are following legal and ethical guidelines for their research. Researchers working abroad will be required to sign a form agreeing to follow the same rules and regulations which apply in the UK. Your donated sample will not be used in animal research, research about termination of pregnancy, or reproductive cloning.

How long will samples be stored?

The samples you donate will stay in the NHS, or with approved researchers until it is all used, or disposed of should you decide to withdraw your consent. All samples will be disposed of lawfully and respectfully, and a record will be kept of this. If you decide to withdraw consent, you can contact your local BioResource team, or contact us on the telephone number or email address in the "Further Information" section.

Will my taking part be confidential?

Yes, only the local BioResource staff will be able to identify you. They will abide by the Data Protection Act 1998 at all times and make sure your name, address, and any other information that would identify you are removed from your sample and questionnaire before it is given to any researchers. All electronic information will be kept secure, and all written information will be held in locked filing cabinets.

Will researchers carry out genetic tests on my sample?

Genetic testing of your DNA may be carried out on your samples, including whole genome sequencing. Whole genome sequencing means studying the complete pattern of the DNA to help understand the biology of genes. A lot of research today focuses on the study of genetic material from healthy individuals compared to people with known diseases. The variations found are important as they help us understand how these differences affect our health. This in turn helps in the development of new drugs and treatments.

The results of these tests cannot be traced back to you, and will only ever be used for research and education.

What if there is a problem?

If you believe that you have been harmed in any way by taking part in this study, speak to the research team in the first instance. If you are still unhappy, you have the right to pursue a complaint and seek any resulting compensation through NHS Lothian which is acting as the research sponsor. Details about this are available from the research team. NHS Lothian are sponsoring this study and as such, you have the right to pursue a complaint through the usual NHS process. To do so, you can submit a written complaint to the Patient Liaison Manager, NHS Lothian Complaints Office, 2nd Floor, Waverley Gate, Edinburgh telephone 0131 465 5708. Note that the NHS has no legal liability for non-negligent harm. However, if you are harmed and this is due to someone's negligence, you may have grounds for a legal action against NHS Lothian, but you may have to pay your legal costs.

Who has reviewed the study?

The Grampian Committee on Medical Research Ethics, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research together with any relevant medical records, be made available for scrutiny by monitors from NHS Lothian whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

Further Information

If you have any further questions, please contact your local BioResource team or:

Dr Charlie Lees, Chief Investigator, Consultant Gastroenterologist,
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We will endeavour to supply this information in different languages and formats if requested.

Thank you for taking the time to read this Information Sheet and for considering taking part in this study.