



Participant Information Sheet

Inclusion in National Inflammatory Bowel Disease Twin & Multiplex Registry

We are inviting you to take part in the UK IBD Twin & Multiplex registry. Before you decide, it is important that you understand why the database is being set up and what it will involve. Please take time to read the following information carefully and if you wish discuss it with us, your friends and relatives or your GP. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the database?

There is evidence that there is a genetic component involved in the development of inflammatory bowel disease (Crohn's and Ulcerative Colitis). Twins give us a rare insight into the relative roles of genes and environment regarding the development of disease. In order for us to further research the importance of genetic factors it is useful for us to learn more about twin pairs when one or both are affected by IBD. We would like to have contact details and medical history of both twins. At a future date members of the database may be invited to take part in further studies. However there would be no obligation to participate.

Why have I been asked to participate?

You have been asked to participate in this study because we believe you are a twin and either yourself or your twin, or both, have Crohn's disease or Ulcerative Colitis.

If I were to participate in the database what would it involve?

If you decide to take part we will ask you and your twin permission to look at your medical records and ask you to both complete a questionnaire. We would inform your GP and IBD specialist that you are contributing to the database. We will also ask them to complete a short questionnaire about your health. We will put this information together to form a database of twins in the UK with inflammatory bowel disease.

Do I have to take part?

No, it is entirely up to you whether or not you take part, and you are free to withdraw your details at any point. If you do decide to participate, we will give you a copy of this information leaflet to keep, and you will be asked to sign a consent form. Whether or not you take part will not affect the standard of care you receive.

What are the possible benefits of taking part?

It is hoped that the information we obtain will help improve the treatment of Crohn's and Ulcerative Colitis in the future. However there are no direct benefits.

Are there any risks?

No, there are no risks from taking part in this database. Your current treatment will not be affected. It will not affect your ability to obtain health insurance.

If I participate will my personal medical information be kept confidential?

All information that is collected about you during the course of the project would be kept strictly confidential. Paper copies of questionnaires and medical records will be kept within a locked office. Electronic information will only be accessible by doctors and research staff directly involved with this database.

How would the database be used?

The database would be used to look for trends which might help explain why some pairs of twins both develop IBD whereas in others only one twin is affected. It would also be used to store your contact details, so we would be able to invite you to participate in future research. There would be no obligation to participate in any further studies.

Individual data will not be made available to participants unless the results could potentially impact on the individual's clinical care. Results would then be shared with the participant and their GP. This decision would be made by senior gastroenterologists who manage the database.

Will I be paid for taking part in the database?

We are unfortunately unable to pay people for taking part.

Who has reviewed the database?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This database has been reviewed and given favourable opinion by NRES Committee South Central Oxford C.

Who is organising and funding the database?

This study is funded by an unrestricted educational grant from a family foundation – The Jessie and Thomas Tam Charitable Foundation and from Genentech Inc.

I have some further questions, who can I ask?

If you would like any further information, (by phone or email or letter), please contact:

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