



PARTICIPANT INFORMATION SHEET AND CONSENT FORM FOR PARENT AND GUARDIAN

Joining the UK Inflammatory Bowel Disease Twin and Multiplex Registry

We are inviting your child to join the UK Inflammatory Bowel Disease Twin and Multiplex Registry. Before you decide whether you would like your child to take part, it is important for you to understand what the registry is, why it is being set up and what joining will involve.

We would also like your child to understand what joining the registry involves. As such we have provided information leaflets for children aged 7-11 and aged 12-17. We will not include the details of children and young people within the registry without parental consent. We also want to be sure your child is happy to participate, and therefore ask children aged 7 or above to sign an assent form in addition to parental consent.

Please take time to read the following information carefully and if you wish discuss it with us, your friends and relatives or your GP. Of course also discuss the registry with your child. Ask us if there is anything that is not clear, or if you would like more information. Take your time to decide whether or not you and your child are both happy to participate. If you have more than one child who would like to join the registry, we ask that you fill in a separate consent form for each child.

What is the purpose of the registry?

In recent years our understanding of Crohn's Disease and Ulcerative Colitis has greatly increased. However there are still significant gaps in our knowledge. Twins provide us with a rare insight into the relative importance of genetic and environmental factor in the development of Inflammatory Bowel Disease (IBD). "Multiplex" families, where three or more relatives have a diagnosis of IBD, have also been invaluable in understanding genetic components to these diseases.

We hope that by further studying twins and Multiplex families we will learn more about why these diseases develop. Ultimately this knowledge will aid the development of new treatment options. As such we have developed a UK IBD Twin and Multiplex Registry. This registry holds information about the medical history and lifestyle of all members. It also holds up to date contact details. From time to time we

invite members to participate in research studies; however there is no obligation to participate, the information itself is very valuable.

When advertising for the registry several parents came forward to ask if their children with IBD could take part. We believe research should be as inclusive as possible. As such we have expanded the registry to include children and young people.

Why has my child been asked to participate?

Your child has been asked to participate in the registry because they are either part of a twin pair, where one or both twins have been diagnosed with IBD, or because they are part of a “Multiplex” family. Multiplex families are defined as families where three or more first degree relatives have been diagnosed with Crohn’s Disease or Ulcerative Colitis.

If my child were to participate in the registry what would it involve?

If you and your child would like to take part we will ask your permission to look at your child’s medical records and ask you to complete a questionnaire about their health. We would inform their GP and IBD specialist that they are contributing to the registry. We will confirm that you are happy for us to tell you about research studies we are running.

Does my child have to take part?

No, it is entirely up to you and your child whether or not you take part, and you are free to withdraw their details at any point. If your child is old enough to understand what being part of the registry entails, we require both of you to be happy for them to join. If you 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. If your child is 7 or older we will provide them with an additional age appropriate participant information form, and ask them to sign an assent form if they are in agreement with joining the registry. Whether or not your child takes part will not affect the standard of care they receive.

What are the possible benefits of taking part?

It is hoped that the information we obtain will help us discover more about Crohn’s Disease and Ulcerative Colitis and will therefore improve treatment of these diseases 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 child’s 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 and your child will 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 registry.

How is the registry used?

The information within the registry is used to look for trends which might help explain why some pairs of twins both develop IBD whereas in other families only one twin is affected. Similarly, the database will be used to look for trends in multiplex families. From time to time we invite members of the registry to participate in research studies. There is no obligation to participate.

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 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:

- Dr Hannah Gordon / Study Co-Investigator
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CONSENT FORM – PARENT OR GUARDIAN

IBD Nixon Twin and Multiplex Registry

Researchers: Dr Marcus Harbord / Dr Hannah Gordon

Please initial box:

1. I confirm that I have read and understand the information sheet dated 25th Feb 2014 for the above database, have had the opportunity to ask questions, and agree for my child to take part in the research.

2. I understand that my participation is voluntary and that my child and I are free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

3. I understand that sections of my child's medical notes may be looked at by responsible individuals from the study sponsor or from regulatory authorities, where it is relevant to this research. I give permission for these individuals to have access to my child's records.

4. I understand that I will be asked to fill in a short questionnaire asking for details of my child's medical history

5. I understand that my GP and IBD specialist will be informed that I am participating in the database. They may be asked to complete a questionnaire asking for details of my medical history

6. I understand that my personal details, including my telephone number, email and address will be stored within the database

7. I understand that I may be invited to participate in research studies in the future, but that I am under no obligation to participate.

I give my permission to take part in the IBD Twin Database

Name of Parent/Guardian Name of Child Date Signature

Please complete both copies. Keep one for your own records and return the second in the prepaid envelope. If your child is aged 7 or over please also return a copy of the assent agreement form if they are happy to participate.