Subject Information for Participation in Medical- Scientific Data Collection

EUROKIDS Paediatric Inflammatory Bowel Disease Registry

Introduction

Dear ,

With this letter, we ask you to participate in a research study, the EUROKIDS registry. Participation is completely voluntary, so your written permission, alongside both your parents'/guardians', is required to participate.

We are approaching you because you have recently been diagnosed with Crohn's disease or ulcerative colitis (both are forms of inflammatory bowel diseases (IBD)).

Before you decide if you want to participate in this study, we will explain to you what this study is about. Read this information carefully and ask your doctor for an explanation if you have any questions. You can also ask the independent expert named at the end of this letter for additional information and discuss it with your parents/guardians, friends, or family.

General information about participating in such a study can be found on the website of the national government: [add national website address if applicable]

1. General Information

This study was initiated by a group of experts in paediatric IBD (the Porto group) from the European Society for Paediatric Gastroenterology Hepatology and Nutrition (ESPGHAN). Collectively the study is being conducted by doctors in over 50 paediatric hospitals across countries in Europe and Israel. The study is coordinated and organised from the Erasmus MC Sophia Children's Hospital in Rotterdam, the Netherlands. The Medical Ethics Review Committee in Erasmus MC has approved this study. [please add/mention here approval by your local Ethics Committee]

2. Background and Purpose of the study

In 2014, the Porto group has made some new rules on how to correctly diagnose IBD in children and adolescents. This study is about collecting data of all children and adolescents with IBD in a web-based registry. The aim is to check how the diagnosis was made and exactly what type of IBD is present in each patient. By doing this, we will implement the new diagnostic rules and check if they were used in the right way. By combining all these data, we will create a European database that will help us improve the way we make a diagnosis in new patients.

3. What it means to participate

If you participate in this study, data will be collected from your patient file, such as your age at diagnosis, symptoms, height and weight, and everything that was seen during your first endoscopy and in the biopsies that were taken at that moment. This data will be entered into the registry and be stored in the database. We will only collect data from your file that concern your bowel disease, and only at or around the time you were diagnosed with IBD.

4. What is expected of you

You do not have to do anything or come to the hospital for extra examinations. All that is needed is permission to access your file and enter the data into the web-based registry. There is no follow-up data required for this registry, so no other information other than what is normally collected is used.

5. Possible inconveniences

There are no inconveniences for you; you will not even notice that you are in the study (besides signing this consent form) as there is nothing extra that you have to do or undergo.

6. Potential Pros and Cons

Participating in the study has no personal advantages and/or disadvantages.

7. If you do not want to participate or want to stop the study

You decide, alongside your parents/guardians, whether you want to participate in the study. If you do not want to participate, you will still be treated for your illness in the usual way. If you and your parents/guardians change your minds about participation, we will remove your data from the database.

8. Use and retention of your data

For this research, your personal data will be collected. This concerns information such as your data of birth (month, year) and your health. Though personal data is asked for, your name will not be entered into the registry.

<u>Confidentiality of your data</u>

To protect your privacy, your data is assigned a patient number. The name and other information that can directly identify you is not entered into the registry, so all participating centres cannot identify you based off the data entered. Data can only be traced back to you with an individual keycode, and only your local research facility can access this. Even in reports and publications based off the data collected, it will not be possible to trace the data back to you.

<u>Data retention period</u>

Your records will be kept at the registry for 15 years.

If you have any questions or complaints about the processing of your personal data, we recommend that you first contact the research location.

9. No Compensation for participating

You will not be paid for participating in this study.

10. Do you have any questions?

If you or your parents/guardians have any questions, please contact the doctor entering you into this registry. If you have any complaints about the study, you can discuss this with the researcher or your attending physician. If you prefer not to do this, you can contact the complaints committee of your hospital. All contact information can be found in Appendix A.

11. Signing the consent form

When you have had sufficient reflection time, you and your parents/guardians will be asked to decide whether to participate in this study. If you all give permission, we will ask you all to confirm this in writing (in Appendix B). By your written consent, you indicate that you have all understood the information and agree to participate in the study. Both you and your doctor will receive a signed version of this consent form.

Appendix A: Contact details for [fill in name of your center here]

[fill in appropriate names etc below]

Principal Investigator
Name:
Email address:
Telephone number:

Research Nurse
Name:
Email address:
Telephone number:

Independent Physician
Name:
Email address:
Telephone number:

Complaints Committee
Name:
Email address:
Telephone number:

Appendix B: Consent form

Consent form for patient

I have been asked to give permission for myself to participate in this medical-scientific study for the EUROKIDS prospective, web-based registry:

- I have read the information letter and had a chance to ask questions which were sufficiently answered. I had enough time to decide if I want to participate.
- I have consulted my parents/guardians
- I know that taking part is voluntary. I also know that I can decide at any time that I stop participating. I do not have to give a reason for that.
- I give permission for the collection and use of my data
- I agree that I will participate in this study

Name of participant: Date of birth: __ / __ / __

Signature: Date: __ / __ / __

Consent form for parents/guardians

I have been asked to give permission for the following person/my child to participate in this data collection for a prospective, web-based registry of paediatric Inflammatory Bowel Disease:

Name parent 1/guardian 1:
Signature: Date: __ / __ / __

Name parent 2/guardian 2:
Signature: Date: __ / __ / __

For the investigator

I hereby declare that I have fully informed the above person(s) about the said investigation

Name of investigator (or their representative):

Signature: Date: __ / __ / __

You will receive this information letter, together with a signed version of the consent form.