Subject Information for Participation in Medical- Scientific Data Collection

EUROKIDS Paediatric Inflammatory Bowel Disease Registry

Introduction

Dear parent of ,

With this letter, we ask for your child to participate in a research study, the EUROKIDS registry. Participation is completely voluntary, so your written permission on behalf of your child is required to participate.

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

Before you decide if you want your child to participate in this study, we will explain to you what this study is about. Read this information carefully and ask your child's 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 partner, 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 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 give your child permission to participate in this study, data will be collected from their patient file, such as their age at diagnosis, symptoms, height and weight, and everything that was seen during their 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 child's file that concern their bowel disease, and only at or around the time they were diagnosed with IBD.

4. What is expected of you

You and your child do not have to do anything or come to the hospital for extra examinations. All that is needed is permission to access their 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 or your child; your child will not even notice that they are in the study (besides for your signing of this consent form) as there is nothing extra that they 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

It is your decision for if your child participates in the study. If you do not want them to participate, they will still be treated for their illness in the usual way. If you want your child to stop participating, we will remove their data from the database.

8. Use and retention of your data

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

<u>Confidentiality of your data</u>

To protect your child's privacy, their data is assigned a patient number. The name and other information that can directly identify them is not entered into the registry, so all participating centres cannot identify them based off the data entered. Data can only be traced back to your child 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 your child.

<u>Data retention period</u>

Your child's records will be kept at the registry for 15 years. If you have any questions or complaints about the processing of their 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 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 child's attending physician. If you prefer not to do this, you can contact the complaints committee of your child's hospital. All contact information can be found in Appendix A.

11. Signing the consent form

When you have had sufficient reflection time, you will be asked to decide whether to allow your child to participate in this study. If you give your written consent (in Appendix B), you indicate that you have understood the information and agree for your child 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 parents/guardians

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

- 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 my child to participate.
- I know that taking part is voluntary. I also know that I can decide at any time for my child to stop participating. I do not have to give a reason for that.
- I give permission for the collection and use of my child's data
- I agree that my child will participate in this study

Name of participant (child): Date of birth: __ / __ / __

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.