The Children's Hospital of Philadelphia®

## Informed Consent Form and HIPAA Authorization

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| **Study Title:** | A Randomized Pilot Study of Fundamental Modification of the Gut Microbiota in the Treatment of Refractory Crohn's Disease (Holiday) |
| Version Date: | March 12, 2020 |
| Consent Name: | Group 2 Verbal Informed Consent Form |

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| **Principal Investigator:** | Lindsey Albenberg | Telephone: (215) 590-1680 |
| **Emergency Contact:** | On-call GI Attending | Telephone: (215) 590-1680 |

You, or your child may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

In the sections that follow, the word "we" means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word "you" refers to your child.

### Why are you being asked to take part in this study?

You are being asked to take part in this research study because you are undergoing a polyethylene glycol bowel lavage (more commonly known as a "bowel cleanout") in preparation for a clinically indicated GI endoscopy (more commonly known as a "scope").

### What is the purpose of this research study?

Our bodies carry around trillions of tiny bacteria, fungi and viruses (called 'microbes') in many places on and inside of our bodies, such as the skin, the mouth, nose and gut. All of the different kinds of microbes that live on and inside of us, taken together, are called the "human microbiome."

Scientists want to know more about the microbiome in children with inflammatory bowel disease (IBD). Scientists have found that they may have differences in their gut microbiome.

This research study is a part of a larger clinical trial which aims to determine whether a unique study drug combination can help children with IBD better respond to medications they already take for their disease.

There will be two groups within the study. The first group (called Group 1) will take the study drug regimen, which will include medications that target the gut microbiome. Also, participants will have a bowel cleanout. We will then look at the gut microbiome and levels of gut inflammation before and after taking the study drug.

The other group (Group 2) of the study will not receive any study drug. You are being asked to participate in Group 2. The purpose of this group is help us understand the effect that a bowel cleanout alone has on the presence of gut microbes and gut inflammation. We will compare both the microbiome and inflammation present in stool samples before and after bowel cleanout. Learning more about its relationship with the gut microbiome and gut inflammation may help us better understand the results of the main clinical trial and develop new therapies for children with IBD.

**How many people will take part?**

About 60 individuals will take part in this study.

## What is involved in the study?

If you agree to take part in the study, you will be asked to collect a baseline stool sample prior to completing your clinically indicated bowel cleanout. Approximately 5 days after your procedure, you will be asked to submit another stool sample. The final stool sample will be collected 12 days after your procedure. We will use your samples in order to prepare and study DNA from the microbe samples. Additionally, we will be testing for the levels of a protein called calprotectin, which is present in stool when your GI tract is inflamed. Your participation in the study will not involve any additional hospital visits.

**How long will you be in this study?**

If you agree to take part, your participation will last for up to 2 months and will involve three study visits.

**What are the study procedures?**

Some of the procedures in this study will be repeated several times. Tests that are part of your regular, routine medical care will continue to be performed. The study involves the following tests and procedures:

Stool Test: You will be asked for a sample of your stool 3 times during the study. Stool will need to be collected both prior to and after the bowel cleanout in preparation of your GI procedure. Stool sample collection kits and directions for their use will be provided to you. Stool sample collection kits can be mailed back if you will not be coming to CHOP for any appointments within the timeframe of the study. We will use your samples to prepare and study DNA from the microbes present in your stool. We will also use your stool samples to perform a fecal calprotectin test which is used to measure intestinal inflammation. If stool samples are not collected in accordance with the instructions provided, you may be asked to repeat sample collection.

Medical Record Review: We will review your medical record and collect information related to your disease history and demographic information. Additionally, we will collect lab values and information related to your medical conditions and treatments. We will collect this data from your medical record until the end of the study.

During the study, we will collect stool samples from you. By agreeing to participate in the study, you agree to give these samples to CHOP for research purposes.

**Visit Schedule**

| Visit | Main Procedures | Duration |
|---|---|---|
| Visit 1, Baseline (prior to bowel cleanout) | Consent, Medical Record Review, Stool Sample Collection | 1 hour |
| Visit 2, Day 5 (post-procedure) | Medical Record Review, Stool Sample Collection | 30 minutes |
| Visit 3, Day 12 (post-procedure) | Medical Record Review, Stool Sample Collection | 30 minutes |

## What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your regular doctor.

As with any study involving collection of data, there is the possibility your confidential information will be shared with others. Every precaution will be taken to secure your personal information to ensure confidentiality.

**Risks associated with study stool collection:**

Any stool sample may contain germs that spread disease. It is important to carefully wash your hands and use careful handling techniques to avoid spreading infection.

**Risks associated with data collection:**

Sharing your information can risk a breach of confidentiality. However, your name will not be shared outside of CHOP. We will do our best to keep your information confidential. A separate list will be maintained that links each participant's name to the study identification number for future reference and communication.

While we will take every precaution we can to keep your identity confidential, there is a small risk that some of the information we collect from you or learn from studying the DNA in your microbes or your own DNA (which can be mixed with the DNA of your microbes) could be linked back to you. Although there are no current methods that people can use to identify you from the DNA in your microbes and your own DNA, we cannot guarantee that there will not be new techniques developed in the future that could do this.

## Are there any benefits to taking part in this study?

There will be no direct benefit to you from taking part in this study. The knowledge gained from this study may help doctors better understand how a bowel clean out affects the gut microbiome and inflammation. This will help us better understand the results of the main clinical trial and develop new therapies for children with IBD.

## Do you need to give your consent in order to participate?

If you decide to participate in this study, you must verbally agree. A copy of your signed consent form will be provided upon request.

**What are your responsibilities?**

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study.

**What happens if you decide not to take part in this study?**

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP.

If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

**Can you stop your participation in the study early?**

You can stop being in the study at any time. You do not have to give a reason.

## What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. This will include information from medical records, procedures, and tests. Information related to your medical care at CHOP will go in your medical record. Medical records are available to CHOP staff. Staff will view your records only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. Laboratory test results will appear in your medical record. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data or samples. These groups include:

- Members of the research team and other authorized staff at CHOP and UPenn
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.
- The Broad Institute in Boston, Massachusetts, who is sponsoring this research.
- The National Institutes of Health who is also sponsoring this research.
- The Food and Drug Administration

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this

document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

A Certificate of Confidentiality (CoC) issued by the NIH covers this research. A CoC helps protect your identifiable information and biological samples.

A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information or biological samples for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

If you consent, your information or biological samples could be shared for:

- your medical treatment and/or for use by your insurance company
- other purposes not connected with this research.

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The NIH may need information to assess this project. Also, the US Food and Drug Administration (FDA) may need information.
- You can still share information about yourself. You can also freely discuss your involvement in this research.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.
- Some information from this study must go in your medical record.
- Your information and biological samples may be shared for other research.

## Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Lindsey Albenberg
The Children's Hospital of Philadelphia
Department of Gastroenterology, Hepatology and Nutrition
Roberts Center, 14-140
2716 South St, Philadelphia, PA 19146

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

**Additional Information**

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study.

## Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance.

**Will there be any additional costs?**

There will be no additional costs to you by taking part in this study.

**Will you be paid for taking part in this study**?

If you decide to participate, you will be compensated $10.00 for each stool sample. If you complete all three sample collections, you will be compensated an additional $70.00. You may be compensated up to $100.00 for participating in the study.

Payment will be in the form of a debit card. If you receive payment using a bankcard. The bank will have access to identifiable information. If samples are collected improperly and you are asked to repeat sample collection, you will not be compensated for repeat sample collections.

**Who is funding this research study?**

The National Institutes of Health and the Broad Institute are providing funding for this study.

The Children's Hospital of Philadelphia is also funding this research.

Please ask Dr. Albenberg if you have any questions about how the study is funded.

## What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. Lindsey Albenberg at 215-590-1680. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**Documentation of Verbal Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research**

_____
Name of Subject

The research study and consent form was explained to:

_____ _____
Person Providing Consent Relation to subject:
☐ Parent ☐ Legal Guardian ☐ Self

The person who provided consent confirmed that all of their questions had been answered and they agreed to their/their child's participation in this research study.

They confirmed that they were legally authorized to consent to their/their child's participation.

They agreed to let CHOP use and share their/their child's health information.

_____ _____
Person Obtaining Consent Signature of Person Obtaining Consent

_____
Date

## Documentation of Verbal Assent to Take Part in this Research Study

**For adults with diminished capacity capable of providing assent:**

I have explained this study and the procedures involved to _____ in terms he/she could understand and that he/she freely assented to take part in this study.

| | |
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| Person Conducting Assent | Signature of Person Conducting Assent |
| | Date |

**For adults with diminished capacity unable to assent:**

I certify that _____ was not capable of understanding the procedures involved in the study sufficiently to assent to study participation.

| | |
|---|---|
| Person Responsible for Conducting Assent | Signature of Person Responsible |
| | Date |