Boston Children's Hospital

RESEARCH CONSENT FORM

This section only to be edited by IRB office.

Use Plate or Print:

MRN#:

DOB:

Subject's Name:

Gender:

Protocol Title: Active Management of Iron Deficiency Anemia in Patients with IBD

Principal Investigator: Paul A. Rufo, MD, MMSc

Please check one of the following:

_____ You are an adult participant in this study.

_____ You are the parent or guardian granting permission for a child in this study.

If the participant is a child the use of "you" refers to "your child"

This consent form gives you important information about how you may play a role in this research study. A research study helps scientists and doctors learn new information to improve medical practice and patient care.

Participation in this research study is voluntary. You are free to say yes or no and your decision will not impact the care you receive at Boston Children's Hospital. You can withdraw from the study at any time. A description of the study and its risks, potential benefits and other important information are included in this consent form. Please read this consent form carefully and take your time making a decision. The form may contain words that you do not understand. Please ask questions about anything you do not understand. We encourage you to talk to others (for example, your friends, family, or other doctors) before you decide to participate in this research study.

How are individuals selected for this research study?

You are being asked to participate in this research study because you have ulcerative colitis, Crohn disease, or Indeterminate Colitis and have been identified as suffering from iron deficiency. As part of your clinical care, the GI physicians helping to take care of you haveprescribed IV iron (INFeD) or oral iron (Ferrous sulfate).

Why is this research study being conducted?

The doctors in the Gastroenterology Division at Boston Children's Hospital (BCH) are doing a research study to try to develop better methods to diagnose and monitor patients with iron deficiency.

Iron is an important nutrient in the body and plays a role in the creation of red blood cells and how your body generates energy. Iron is typically absorbed from the food that we eat. However, this is a very inefficient

process and only about 1% of the iron that we eat can be absorbed in the intestine. When patients have inflammatory bowel disease (Crohn disease or ulcerative colitis) they are at risk for the development of iron deficiency through poor iron intake or increased iron losses in the stool. Physicians can try to treat this by prescribing oral iron supplements or intravenous iron.

The availability of intravenous iron has made possible the delivery of much more iron, in a much shorter period of time. This is now the recommended method of iron treatment for patients with IBD in Europe.

This study will be specifically looking at patients who are receiving *IV iron (INFeD)* or *oral iron (Ferrous sulfate)* as part *of clinical care.*

Who is conducting this research study, and where is it being conducted?

This study is being done through the Center for Inflammatory Bowel Disease at BCH by Dr. Paul Rufo, his scientific collaborators, and his Research Study Coordinators.

How many people will participate in this research study?

Approximately 100 patients will take part in this study at BCH.

What do I have to do if I am in this research study?

The GI physicians caring for you have prescribed either *IV iron (INFeD)* or *oral iron (Ferrous sulfate)* as part *of clinical care.*

As part of this research study you will be asked to do the following:

1. Completethe Ped QoL questionnaire: Since we will be assessing individual patient responses to this therapy, we will be asking you to complete questions about how you're feeling and how many GI symptoms you have been experiencing. You will complete the first set of brief questionnaires during at the time of the iron infusion (or the first dose of oral iron), and then at subsequent visits in the outpatient clinic. You may complete these questionnaires at home, and you will not need to return to BCH to complete participation in this study.

   The Ped QoL questionnaires have been developed specifically for use in studies in children. These forms will take no more than a few minutes to complete.

2. Medical Record review: In addition, we will be asking for your permission to review the reports of any previous or future endoscopic studies. This includes studies in which a flexible telescope was inserted

into your mouth and used to examine the stomach and small intestine (referred to as upper endoscopy). Other endoscopic studies involve insertion of a flexible telescope into your bottom or anus, and examination of the large intestine (referred to as colonoscopy). We will also be reviewing the medical records of enrolled subjects to review any previous blood, urine, stool, or x-ray studies that have been done to evaluate your/your child's intestinal disease. No additional studies or trips to the hospital will be required for participation in this study.

Study Visit Timeline	Time of INFeD Infusion	First Outpatient Visit	Second Outpatient Visit	Third Outpatient Visit	Fourth and Subsequent Outpatient Visit for 12 months
Consent /Assent	X				
Medical Record Review	X	X	X	X	X
Quality of Life Questionnaires	X	X	X	X	X

What are the risks of this research study? What could go wrong?

RISKS AND DISCOMFORTS:

Risks Related to Questionnaires:

You may be asked questions in the Pediatric Quality of life questionnaire that make you uncomfortable or cause you to remember situations that were upsetting to you. You may become frustrated if you are asked questions during completion of the survey that you do not know how to answer. You may not be able to answer all the questions and you do not need to answer any questions that you do not wish to answer. If you become upset at any time, you can stop the survey. We will also offer to have you speak to someone about how you are feeling.

Risks Related to Medical Record Review:

We will be reviewing you/your child's medical records to collect information that will allow us to assess the effect of iron therapy. Any collected information will be stored in a locked location or on a password-protected site behind the Children's Hospital firewall. As such, the likelihood that there will be a breach of confidentiality would be minimal.

What are the benefits of this research?

POTENTIAL BENEFITS:

We will be investigating the impact of iron administration on blood and quality of life outcomes. Participation in this study will therefore provide clinicians with information about the relationship between iron-deficiency and quality of life in children and young adults with IBD. The responses that you provide may be useful to review with your clinician, as this information may help identify symptoms of iron deficiency in the future.

It is our hope that data from this study will help physicians to develop newer treatment plans to address iron deficiency in patients with IBD.

Are there costs associated with this research? Will I receive any payments?

You will not be paid for participation in this study.

The information that you provide us will be stored with identifiers, such as your name or medical record number. The research staff will have a list to know which sample is linked to which participant and this list will be kept confidential in a secure location. If the research investigator distributes your samples to other researchers or institutions, they will be labeled with a research code without identifiers so that you cannot be identified.

If you have questions about how information for this study will be stored or would like your information to be removed from the study, please let us know.

It is possible that the information that we collect may be made available to other hospitals, universities, and businesses for further research or to create commercial products, research tools, or inventions that have value. If this were to occur, Boston Children's Hospital and/or the research investigator might receive financial benefits. As in all research studies, the hospital has taken steps designed to ensure that this potential for financial gain does not endanger research participants, or undercut the validity and integrity of the information learned by this research. Further, Boston Children's Hospital believes that devoting payments we receive to research and health care is the best way to benefit patients as whole, so we do not transfer those payments to research participants.

Why would I be taken off the study early?

The research investigator may take you out of this study at any time. This would happen if:

- The research is stopped.
- You are not able to the routine laboratory studies required for management of your/your child's IBD.

If this happens, the research investigator will tell you.

Other information that may help you:

Boston Children's Hospital has developed a web-based, interactive educational program for parents called "A Parent's Guide to Medical Research." To find out more about research at Children's, please visit the program at www.researchchildren.org.

Boston Children's Hospital is interested in hearing your comments, answering your questions, and responding to any concerns regarding clinical research. If you have questions or concerns, you may email IRB@childrens.harvard.edu or call (617) 355-7052 between the hours of 8:30 and 5:00, Monday through Friday.

Who may see, use or share your health information?

A copy of this consent form will be placed in your medical record. If you do not have a medical record at Boston Children's Hospital, one will be created for you.

The results of the tests performed for research purposes will not be placed in your medical record. Because of this, it is unlikely that others within the hospital, an insurance company, or employer would ever learn of such results.

Contact for Future Studies: Your participation in any research is completely voluntary and you should feel no pressure to participate if you are contacted about another research study.

Please check and initial one of the options below regarding future contact about other research done by us or other researchers we are working with (collaborators).

_____ ☐ Yes, I may be contacted about participating in other research projects studying Inflammatory Bowel Disease or related conditions. I give permission for my contact information (name and mailing address and/or phone number) to be given to other researchers working with the study investigator at Boston Children's Hospital.

_____ ☐ No, I do not want to be contacted about other research projects. **Do not** give my contact information to the staff of any other research studies.

What should you know about HIPAA and confidentiality?

Your health information is protected by a law called the Health Information Portability and Accountability act (HIPAA). In general, anyone who is involved in this research, including those funding and regulating the study, may see the data, including information about you. For example, the following people might see information about you:

- Research staff at Boston Children's Hospital involved in this study;
- Medical staff at Boston Children's Hospital directly involved in your care that is related to the research or arises from it;
- Other researchers and centers that are a part of this study, including people who oversee research at that hospital;
- People at Boston Children's Hospital who oversee, advise, and evaluate research and care. This includes the ethics board and quality improvement program;
- People from agencies and organizations that provide accreditation and oversight of research;
- People that oversee the study information, such as data safety monitoring boards, clinical research organizations, data coordinating centers, and others;
- Sponsors or others who fund the research, including the government or private sponsors.
- Companies that manufacture drugs or devices used in this research;
- Federal and state agencies that oversee or review research information, such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities;
- People or groups that are hired to provide services related to this research or research at Boston Children's Hospital, including services providers, such as laboratories and others;
- And/or your health insurer, for portions of the research and related care that are considered billable.

If some law or court requires us to share the information, we would have to follow that law or final ruling.

Some people or groups who get your health information might not have to follow the same privacy rules. Once your information is shared outside of Boston Children's Hospital, we cannot promise that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect privacy may no longer apply to this information. Other laws may or may not protect sharing of private health information. If you have a question about this, you may contact the Boston Children's Hospital Privacy Officer at (857) 218-4680, which is set up to help you understand privacy and confidentiality.

Because research is ongoing, we cannot give you an exact time when we will destroy this information. Researchers continue to use data for many years, so it is not possible to know when they will be done.

We will also create a code for the research information we collect about you so identifying information will not remain with the data and will be kept separately. The results of this research may be published in a medical book or journal or be used for teaching purposes. However, your name or identifying information will not be used without your specific permission.

Your privacy rights

If you want to participate in this research study, you must sign this form. If you do not sign this form, it will not affect your care at Boston Children's Hospital now or in the future and there will be no penalty or loss of benefits. You can withdraw from the study and end your permission for Boston Children's Hospital to use or share the protected information that was collected as part of the research; however you cannot get back information that was already shared with others. Once you remove your permission, no more private health information will be collected. If you wish to withdraw your health information, please contact the research team.

You may have the right to find out if information collected for this study was shared with others for research, treatment or payment. You may not be allowed to review the information, including information recorded in your medical record, until after the study is completed. When the study is over, you will have the right to access the information again. To request the information, please contact the Hospital's Privacy Officer at (857) 218-4680.

Contact Information

I understand that I may use the following contact information to reach the appropriate person/office to address any questions or concerns I may have about this study. I know:

I can call…	At	If I have questions or concerns about
Investigator: **Paul A. Rufo, MD, MMSc**	Phone: **671-355-2962**	▪ General questions about the research ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Sarah Rogerson or Timothy Yang	Phone: **671-355-2962**	▪ General questions about the study ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints
Institutional Review Board	Phone: **617-355-7052**	▪ Rights of a research participant ▪ Use of protected health information. ▪ Compensation in event of research-related injury ▪ Any research-related concerns or complaints. ▪ If investigator/research contact cannot be reached. ▪ If I want to speak with someone other than the Investigator, Research Contact or research staff.

Documentation of Informed Consent and Authorization

- I have read this consent form and was given enough time to consider the decision to participate in this research.

- This research has been satisfactorily explained to me, including possible risks and benefits.
- All my questions were satisfactorily answered.
- I understand that participation in this research is voluntary and that I can withdraw at any time.
- I am signing this consent form prior to participation in any research activities.
- I give permission for participation in this research and for the use of associated protected health information as described above (HIPAA).

Parent/Legal Guardian Permission (if applicable)

If the child to be involved in this research is a foster child or a ward of the state please notify the researcher or their staff who is obtaining your consent.

■ _____ _____ _____

Date (MM/DD/YEAR) Signature of **Parent or Legal Guardian** Relationship to child

Child Assent

■ _____ _____

Date (MM/DD/YEAR) Signature of **Child/Adolescent Participant**

■ If child/adolescent's assent is **not** documented above, please indicate reason below (check one):

☐ Assent is documented on a separate IRB-approved assent form
☐ Child is too young
☐ Other reason (e.g. sedated), please specify: _____

Adult Participant (if applicable)

■ _____ _____

Date (MM/DD/YEAR) Signature of **Adult Participant (***18+ years)*

Research Investigator /or Associate's Statement & Signature

- I have fully explained the research escribed above, including the possible risks and benefits, to all involved parties (participant /parents/legal guardian as applicable).
- I have answered and will answer all questions to the best of my ability.

- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the research.
- I have provided a copy of the consent form signed by the participant / parent / guardian and a copy of the hospital's privacy notification (if requested).

■ _____ _____

Date (MM/DD/YEAR) Signature of **Research Investigator or Associate**

Witness Statement & Signature

A witness must be present for the entire consent process in the following situations (please check the appropriate box)

☐ The individual cannot read and this consent document was read to the participant or legal representative, **or**

☐ The individual has certain communication impairments that limit the participant's ability to clearly express consent **or**

☐ Situations where the IRB requests a witness be present: please specify _____

I confirm that the information in this consent form was accurately explained to the participant, parent or legally authorized representative, the individual appeared to understand the information and had the opportunity to ask questions, and that informed consent was given freely.

☐ _____ _____

Date (MM/DD/YEAR) Signature of Witness

Or

☐ The individual is not English speaking and, through an interpreter, a short form consent document was presented orally to the participant or legal representative and this consent document serves as the summary for such consent.

I confirm that the information in this consent form was presented orally to the participant, parent or legally authorized representative, in a language they could understand and the individual had the opportunity to ask questions.

☐ _____ _____

Date (MM/DD/YEAR) Signature of Witness