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**CAUTION: IF YOU HAVE PRINTED THIS CONSENT FOR USE WITH PARTICIPANTS, IT IS NOT THE IRBMED APPROVED VERSION.** Access the approved/watermarked consent from the Documents Tab in the main study workspace. The approved/watermarked document *will not* contain this cover page and *will* have the approval watermark present in the header.

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## **INSTRUCTIONS FOR EDITING THIS DOCUMENT**

1. Turn on Track Changes.
2. Make necessary changes in consent, and update the footer intended for study team version control.
3. Upload the revised consent into Section 10-1, maintaining the IRBMED standard naming convention as follows:
  - **Consent - Tracked**
  - **Consent - *Concise Subtitle* – Tracked** (provide a subtitle when there are multiple consents associated with the study)
  - **Assent - Tracked**
  - **Parental Permission/Assent - Tracked**
  - **Parental Permission – Tracked**

### **NOTES:**

Words identified above in bold must not be changed; words identified in italics may be modified by the study team. Informed consent subtitles should be a one or two word descriptor, such as: **Consent – *Genetic* – Tracked** or **Consent – *Blood Draw* - Tracked**.

Each subsequent track changes version should be [stacked](#) on the previously uploaded track changes version.

**DO NOT** delete any documents or stacks of documents from eResearch; these are retained for historical and regulatory reference purposes.

**DO NOT** upload a clean version of the consent.

----- **IRB OFFICE USE ONLY** -----

**Study ID: HUM00124135 / Amendment ID: Ame00099634**

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**Document Finalized: 4/8/2020 5:52 PM**

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# UNIVERSITY OF MICHIGAN

## CONSENT TO BE PART OF A RESEARCH STUDY

### INFORMATION ABOUT THIS FORM

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 the study, and the risks and possible benefits of participating in the study. Parents or legal guardians, who are giving permission for a child, please note: in the sections that follow the word 'you' refers to 'your child'.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

### 1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

**1.1 Study title:** Physician Global Assessment of Colonoscopy Score

**1.2 Company or agency sponsoring the study:** Pediatric Resource Organization for Kids with Inflammatory Intestinal Diseases (PRO-KIIDS)

**1.3 Names, degrees, and affiliations of the researchers conducting the study:**

**Jeremy Adler, MD, MSc, Principal Investigator**, Assistant Professor of Pediatric Gastroenterology and Health Services Research and the Director of the Pediatric Inflammatory Bowel Disease Program at the University of Michigan.

**George Zacur, MD, Co-Investigator**, Assistant Professor of Pediatric Gastroenterology

**Ila Moncion, MS, Study Coordinator**, Clinical Subjects Associate, Pediatric Gastroenterology

**Sally Eder, BA, Study Coordinator**, Clinical Subjects Coordinator, Pediatric Gastroenterology

### 2. PURPOSE OF THIS STUDY

**2.1 Study purpose:** This study has been designed to simplify an endoscopic score for Crohn's disease by comparing current scoring system to our newly developed Physician Global Assessment of colonoscopy Score and see if the new score has favorable rating for usability.

### 3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

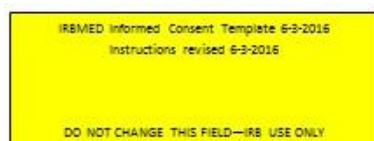
**3.1 Who can take part in this study?**

Patients under 25 who are scheduled to undergo a colonoscopy or have recently undergone colonoscopy for known for suspected Crohn's disease at Mott Children's Hospital for clinical indications.

**3.2 How many people (subjects) are expected to take part in this study?**

30 Adults and 70 children are expected to participate.

### 4. INFORMATION ABOUT STUDY PARTICIPATION



#### 4.1 What will happen to me in this study?

If you are interested in volunteering, our study team will answer questions about the study and go over the study consent. After you complete the consent form, you will continue with your scheduled procedures. Videoing colonoscopies here at C.S. Mott is standard of care and done on everyone, but if you agree to consent, the video will be used for this research study. Any identifying information on the videos will be removed and replaced by a unique study number. This means that there will be no name or other information on the video that can be used to identify you. We may also perform minimal editing of videos if necessary to remove portions of the videos that may contain footage outside of the bowel, or portions where the screen is view is completely obstructed. This will be done to ensure patient confidentiality and improve video quality. We will not remove any portions of video containing colonoscopic views of the bowel. Only the study staff will have access to the code list that links your data or study number to your information. If you/your child have not yet undergone colonoscopy, you will also fill out a one time survey, that has 35 questions about how you feel the 7 days leading up your scope. It should take 5-10 minutes to complete. They can be answered with the help of a parent.

8-10 physicians called “central readers”, from outside the University of Michigan, will be trained in how to perform the scoring, and **will not** know *any* clinical details about you or your case. The central readers will receive the de-identified video which will contain the study number (no name). They will view the colonoscopy in its entirety (except for the parts edited out).

#### 4.2 How much of my time will be needed to take part in this study?

The initial informed consent will require approximately 15-20 minutes. There are **no** follow-up visits or sample collection associated with this study. The colonoscopy will not take longer than it would otherwise take if you were not in the study.

#### 4.3 When will my participation in the study be over?

In addition to the time above, we will collect information from your medical records for an additional 2 years after your participation, this includes any future scopes and histology information—if done for clinical reasons, to monitor disease progress. The entire study is expected to last about 7 years.

#### 4.4 What will happen with my information and/or biospecimens used in this study?

Your collected information may be shared with Crohn’s and Colitis Foundation of America (CCFA). With appropriate permissions, your collected information may also be shared with other researchers here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

May the researchers store your (your child’s) video and use them in the future for further research or educational purposes? (Please check the appropriate box and initial the line beside it.)

[ ] \_\_\_\_\_ YES: I permit the researchers to store my video for future research/education.

[ ] \_\_\_\_\_ NO: I do not want the researchers to use my video for any additional studies or education.

### 5. INFORMATION ABOUT RISKS AND BENEFITS

#### 5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

This study involves minimal risk such as inconvenience, or risk to confidentiality from the study information. The researchers will try to minimize these risks (for example, by removing identifying information). As with any research study, there may be additional risks that are unknown or unexpected.

### **5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?**

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors.

### **5.3 If I take part in this study, can I also participate in other studies?**

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study. That said, this study has minimal risks and is not likely to interfere with other studies. So it is best to discuss with the researchers of both studies if you are considering participating in another study.

### **5.4 How could I benefit if I take part in this study? How could others benefit?**

You may not receive any personal benefits from being in this study. This study has been designed to compare scoring systems based on mucosal healing in Crohn's disease. The potential benefit may be to make future research about pediatric Crohn's disease easier in the future.

## **6. OTHER OPTIONS**

### **6.1 If I decide not to take part in this study, what other options do I have?**

If you do not wish to participate in research, you do not have to. Taking part in this study is completely **voluntary**. If you choose not to participate in this study, it will not affect your healthcare in any way.

## **7. ENDING THE STUDY**

### **7.1 If I want to stop participating in the study, what should I do?**

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information" (below).

### **7.2 Could there be any harm to me if I decide to leave the study before it is finished?**

There is no harm to you if you decide to leave the study before it is finished.

### **7.3 Could the researchers take me out of the study even if I want to continue to participate?**

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

## **8. FINANCIAL INFORMATION**



### 8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1. There are no costs or billing for this study. The colonoscopy that your doctor scheduled is being done for clinical purposes as part of healthcare, so the cost of the colonoscopy itself is not considered part of the study.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care, including the colonoscopy itself.
- Items or services needed to give you study drugs or devices.
- Monitoring for side effects or other problems.
- Deductibles or co-pays for these items or services

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

### 8.2 Will I be paid or given anything for taking part in this study?

You will receive a one time \$25 gift card for allowing us to use the video of your colonoscopy, p

### 8.3 Who could profit or financially benefit from the study results?

No Person(s) or organization(s) have a financial interest in the outcome of this research.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

## 9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

### 9.1 How will the researchers protect my privacy?

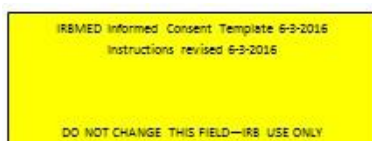
Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. Videos will be assigned a random number before they are analyzed by providers, so they will not know who you are.

Informed consent documents will be kept in a locked filing cabinet and only study team will have access to patient identifier link. Video files will be stored on a secure hospital server. Coded videos will be shared with the Central readers, who will not know any clinical details (name, age, sex, diagnosis, medications).

### 9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study. Study information will only be shared with researchers who are part of the study.

Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:



- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.);
- All records relating to your condition, the treatment you have received, and your response to the treatment;
- Demographic information;
- Personal identifiers;

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study;
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the institutional review board (IRB) may need the information to make sure that the study is done in a safe and proper manner;
- Study sponsors or funders, or safety monitors or committees, may need the information to:
  - Make sure the study is done safely and properly,
  - Learn more about side effects,
  - Analyze the results of the study;
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study;
- The researchers may need to use the information to create a database of information about your condition or its treatment;
- Information about your study participation may be included in your regular University of Michigan Health System (UMHS) medical record;
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes;
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would only be published as combined group results, and would not include any information that would let others know who you are.

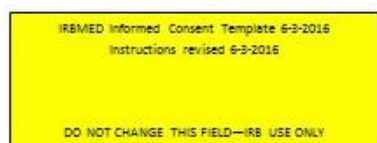
### **9.3 What happens to information about me after the study is over or if I cancel my permission?**

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information;
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are);
- To help University and government officials make sure that the study was conducted properly.

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at <http://www.uofmhealth.org/patient+and+visitor+guide/hipaa>. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).



#### 9.4 When does my permission expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

May the researchers contact you at some time in the future to ask questions and/or discuss whether you would be interested in participating in a future study? (Please check the appropriate box and initial the line beside it.)

\_\_\_\_\_ YES: I agree to allow the study investigators to contact me in the future to ask follow-up questions and/or discuss my interest in participating in these future studies.

\_\_\_\_\_ NO: I do not want the study investigators to contact me in the future.

### 10. CONTACT INFORMATION

#### 10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study;
- Ask a question about the study procedures or treatments;
- Talk about study-related costs to you or your health plan;
- Report an illness, injury, or other problem (you should also tell your regular doctors);
- Leave the study before it is finished;
- Express a concern about the study.

Principal Investigator: Jeremy Adler  
Mailing Address: 300 N Ingalls 618D , Ann Arbor MI, 48109-5456  
Telephone: 734-763-9650  
e-mail: [jeradler@med.umich.edu](mailto:jeradler@med.umich.edu)

Co-Investigator: George Zacur  
Mailing Address: 1500 E Medical Center Dr. MPB D5200, Ann Arbor MI, 48109-5718  
Telephone: 734-763-9650  
e-mail: [gzacur@med.umich.edu](mailto:gzacur@med.umich.edu)

Study Coordinator: Sally Eder  
Mailing Address: 1500 E Medical Center Dr. MPB D5200, Ann Arbor MI, 48109-5718  
Telephone: 734-615-4271  
e-mail: [saleder@med.umich.edu](mailto:saleder@med.umich.edu)

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)  
2800 Plymouth Road  
Building 520, Room 3214  
Ann Arbor, MI 48109-2800  
Telephone: 734-763-4768 (For International Studies: US Country Code: 001)  
Fax: 734-763-1234  
e-mail: [irbmed@umich.edu](mailto:irbmed@umich.edu)

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

## 11. RECORD OF INFORMATION PROVIDED

### 11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)
- The subject will receive a copy of the signed and dated informed consent.

## 12. SIGNATURES

### Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with \_\_\_\_\_. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

\_\_\_\_\_  
Participant's Printed Name

\_\_\_\_\_  
Participant's Signature/Assenting Subject

\_\_\_\_\_  
Date (mm/dd/yy)

\_\_\_\_\_  
Signature of Participant's Parent or Legally Authorized Representative\*

\_\_\_\_\_  
Date (mm/dd/yy)

\* If signed by legally authorized representative, a description of such representative's authority must be provided



**Principal Investigator or Designee**

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

\_\_\_\_\_  
Legal Name

\_\_\_\_\_  
Title

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date of Signature (mm/dd/yy)