

**\*\*\*\*\*DO NOT DELETE OR ALTER THIS PAGE\*\*\*\*\***

**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.

\*\*\*\*\*

## **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**

**Approval Date: 8/20/2019**

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

---

# UNIVERSITY OF MICHIGAN

## ASSENT TO BE PART OF A RESEARCH STUDY

### FOR CHILDREN AGES 10 TO 17

We want to tell you about a research study we are doing and see if you want to take part in it. Research is a way to learn more about something. This is the way we find out if drugs or other treatments are safe and if they work.

- The name of this study is: Physician Global Assessment of Colonoscopy Score
- Study Team: Dr. Jeremy Adler, Dr. George Zacur, and Ila Moncion

It is okay to ask questions about what we are telling you. You can circle or highlight things on this paper you want to know more about. If you don't understand something, just ask us. We want you to ask questions now and anytime you think of them. It is also OK to have a parent / guardian help you with the survey.

We are working to learn more about a scoring system used to look at Crohn's disease.

You are being asked to be in this research study because the current scoring system for a Crohn's scope is too complicated for doctors, so we are comparing it to our new one to see if it works, and see if it is easier for them to use.

For you to be in this study both you and your parent (or guardian) must agree to you being in it. It is the adult's job to make sure the benefits and risks of this study are okay for you. But it is still up to you if you *want* to do it.

Parents and children say "no" for different reasons. It may be that you would miss too many activities or school. It could be the risks seem too great or that the benefits seem too low. Whatever the reason, it is your decision. You will not be treated any differently if you say "no."

If you decide to be in this research and your parent or guardian says yes, this is what will happen:

- We will have you agree to use the video we are already recording, but for research instead of clinical purposes.
- If you haven't already had your colonoscopy, we will ask you to answer 35 questions about how you felt the week before your scope.
- We will look at your doctors records about you for 2 years, to see how you are doing or if you need any more scopes- we will use that video too.
- This research will take just this one visit before you head in to be scoped.

Some of the ways you could be helped are:

- Feel good about helping others

We do not know for sure if you will be helped by being in this study. Also, we could learn something that will help other children with Crohn's disease someday.

There is a chance that during the research you could feel uncomfortable, afraid, lonely, or hurt. We will take steps to help you with these feelings or discomforts. And you can stop at any time if you want to. Some of these risks are:

- Sometimes the questions we ask can make you feel embarrassed/sad/uncomfortable.

You don't have to be in this study if you don't want to. Nobody will be mad at you if you don't want to be in the research study. You can say okay now and you can change your mind later. Just tell the doctor or your parent or guardian if you want to stop at any time. Your doctor will still take care of you if you don't want to be in the study.

I have read this form or someone has read it to me. If I did not understand something, I asked the doctor or the assistant to explain it to me. I can always ask the doctor or the assistant a question about the study if I don't understand something. I will be given a copy of this form.

Please check one box:

**YES**, I want to be in this study and I know I can change my mind later.

**NO**, I do not want to be in this study.

*Child's Name (print legal name):* \_\_\_\_\_

*Child's Signature:* \_\_\_\_\_

*Date of signature:* \_\_\_\_\_ *Age #* \_\_\_\_\_

*Patient ID:* \_\_\_\_\_ *Date of Birth (mm/dd/yyyy):* \_\_\_\_\_

The following should be completed by the study member conducting the assent process if the child agrees to be in the study. Check all that apply.

- The child is capable of reading and understanding the assent form and has signed above as documentation of assent to take part in this study.
- The child is not capable of reading the assent form, but the information was verbally explained to him/her. The child signed above as documentation of assent to take part in this study.
- The child had ample opportunity to have his or her questions answered.

*Printed name of person  
obtaining agreement:* \_\_\_\_\_

*Signature of person  
obtaining agreement:* \_\_\_\_\_

*Date of signature:* \_\_\_\_\_