

# UNIVERSITY OF MICHIGAN CONSENT TO BE PART OF A RESEARCH STUDY

## INFORMATION ABOUT THIS FORM

You 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.

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 check on the box below to indicate your consent. *Before you check the box, 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:** The Effect of Inflammatory Bowel Disease on Students' Adjustment to College

**1.2 Company or agency sponsoring the study:** none

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

Study Team Member	Role	Department (all at University of Michigan)
Ellen Zimmermann, MD	PI	Internal Medicine - Gastroenterology
Jeremy Adler, MD	Co-Investigator	Pediatric GI & Communicable Diseases Dept
Beth Manoogian, MD	Co-Investigator	Internal Medicine Resident
Sameh Bashar Almadani	Co-Investigator	Medical & Public Health Student
Jacob Kurlander	Co-Investigator	Medical Student
Andrace DeYampert	Study Coordinator /Project Manager	Internal Medicine - Gastroenterology

## 2. PURPOSE OF THIS STUDY

**2.1 Study purpose:**

The main goal of this research project is to investigate possible differences in college adjustment between healthy college students and those with Inflammatory Bowel Disease and to see how disease activity affects those differences. To do this, we will develop a website that is easily accessible to students with inflammatory bowel disease (IBD) in order for them to be able to participate in a survey aimed at examining these differences. It has been previously shown that successful adjustment to college is critical for academic success and is associated with success later in life. Living with a chronic disease such as IBD is difficult enough for students without the added challenges and struggles that come with transitioning to college. As a result, these students face a unique set of challenges as they leave home to begin a new life in college. Oftentimes, college-aged students "fall through the cracks" of the healthcare system as they commonly go far from home and are transitioning from pediatric to adult realms of healthcare. Though the number of diseased college students is unknown, it is known that IBD

onset peaks between the ages of 15 and 25 years old. As a result, many young adults are currently coping with the stress of having a devastating chronic illness coupled with the stress associated with transitioning to college. As shown in a pilot study previously conducted at the University of Michigan, the level of disease activity and the severity of the symptoms are strongly associated with difficulty adjusting to college. This is important because adjustment to college has been linked with academic success, graduation rates, and future success in the workplace. We believe our study to be the first to look at the role of Crohn's disease and ulcerative colitis on college adjustment. By taking this study nationwide, we will be able to evaluate a much larger population of students and will be able to see whether this pattern exists across the country. A secondary goal of the research is to help inform the development of more effective interventions for IBD students, to better monitor their disease during college, and to help develop better programs to help them make the transition to college.

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

Taking part in this study is completely **voluntary**. There is no cost to you for participating in this study. 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?**

Undergraduate students at a 4-year residential college or university in the United States, 17 years old or older, with Inflammatory Bowel Disease.

Undergraduate students at a 4-year residential college or university in the United States, 17 years old or older with no health problems.

If you have another chronic illness, such as asthma, diabetes, depression, substance abuse, pregnancy, *uncertain* Inflammatory Bowel Disease, or another major life stressor within the last year, we regret that you cannot participate in this study.

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

300 subjects (100 with IBD and 200 without IBD) are expected to participate from universities and colleges across the country.

**4. INFORMATION ABOUT STUDY PARTICIPATION**

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

Participation in this study involves navigating to the University of Michigan IBD Program website (which is full of useful information including educational resources, health-related information, a chatting forum for sharing experience with other students, and a link to our study). You will choose to participate in the study or not. If you decide to participate, you will complete several surveys regarding your quality of life and adjustment to college. All questions will be multiple-choice. We estimate that it should take no longer than 45 minutes to complete the surveys. We ask that you please complete the survey in it's entirety in order for it to be submitted.

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

We anticipate 45 minutes will be needed to complete the surveys.

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

Upon completion of the surveys, your participation in the study will be over. You may return to the website when patient recruitment is complete to examine the study results as they become available.

### 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?

The known or expected risks are:

- Breach of promise of Confidentiality
  - There is always the small risk involved in any type of electronic research of potential breach of a promise of confidentiality

The researchers will try to minimize these risks by:

- Using no personal identifying information, password-protecting all stored data, and keeping study-related materials in locked cabinets.
- As with any research study, there may be additional risks that are unknown or unexpected.

#### 5.2 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. However, some study subjects, particularly those with IBD or who know someone with IBD, may benefit from our website which is full of useful IBD-specific information including educational resources, health-related information, and a chatting forum for sharing experience with other students.

Possible benefits to society include better understanding of how IBD affects students as they try and adjust to college. The potential benefit of improving college adjustment in IBD-affected students, whether through more aggressive treatment before entering college, better disease monitoring during college, or through better informed interventions for such students, include improved academic success, better career placement, and improved chances of obtaining health insurance.

**6. OTHER OPTIONS**

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

Again, this study is completely voluntary. The alternative is to not participate, in which case there will be no penalty.

**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 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:

- ✓ You become ineligible to participate.
- ✓ 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?**

There are no costs or billing for this study.

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?**

No, you will not be paid for participating in this study.

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

No person or organization has a financial interest in the outcome of the study.

## **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?**

We will use no personal identifying information, password-protect all stored data, and will keep study-related materials in locked cabinets.

### **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 unidentifiable information about you for this study, and is required in order for you to take part in the study. We will take every precaution to keep your information from being linked to you as an individual.

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 to use the information to create a databank of information about your condition or its treatment.
- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.

The results of this study could be published in an article, but 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

## 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 any questions about the study procedures
- Leave the study before it is finished
- Express a concern about the study

→ **Principal Investigator:** Ellen Zimmerman, MD

**Mailing Address:**

Department of Internal Medicine – Division of Gastroenterology  
6520 MSRB I  
1150 W. Medical Center Dr., SPC 5682  
Ann Arbor, MI 48109-5682

**Telephone:** (734) 647-2964

→ **Study Coordinator:** Andrace DeYampert

**Mailing Address:**

1150 W. Medical Center Dr.  
6510 MSRB I, SPC 5682  
Ann Arbor, MI 48109-5682

**Telephone:** 734-764-0507

**Email:** [andraced@umich.edu](mailto:andraced@umich.edu)

You may also express a concern about a study by contacting the Institutional Review Board listed below, or by calling the University of Michigan Compliance Help Line at 1-888-296-2481.

University of Michigan Medical School Institutional Review Board (IRBMED)  
Argus I  
517 W. William  
Ann Arbor, MI 48103-4943

Telephone: 734-763-4768

Fax: 734-615-1622

E-mail: [irbmed@umich.edu](mailto:irbmed@umich.edu)

If you are concerned about a possible violation of your privacy, contact the University of Michigan Health System Privacy Officer at 1-888-296-2481.

*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?**

No documents will be given to you. Your “signature,” as indicated by checking the box below, certifies that you have read and that you understand this informed consent document and are willing to participate.

**12. SIGNATURES**

**Research Subject:**

*I understand the information included on this form. 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 by checking the box below, I am conveying my own free choice to take part in this study as a research subject.*

- Yes
- No