MAYO CLINIC

Name and Clinic Number

Approval Date: **March 31, 2021**
Not to be used after: **March 30, 2022**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Mayo Clinic Inflammatory Bowel Disease Repository

IRB#: 13-000712

Principal Investigator: Dr. William A. Faubion and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep. A copy of this form will be put in your medical record.

If you are signing this consent form for someone else, "you" in the consent form refers to the participant.

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CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator: Dr. William Faubion (MCR) Dr. Michael Picco (MCF) Dr. Shabana Pasha (MCA) **Study Team Contacts:** Study Coordinators: Erin Kammer and Alana English (MCR) Thomas Morse (MCF) Jody Devine (MCA)	**Phone:** (507) 284-2468 (904) 953-0131 (480) 301-6990 **Phone:** (507) 538-9459 (904) 953-4359 (480) 301-6767 **Institution Name and Address:** Mayo Clinic 200 First Street SW Rochester MN 55905	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Subject Advocate **(The RSA is independent of the Study Team)**	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information
Patient Account Services	**Toll-Free:** (844) 217-9591	▪ Billing or insurance related to this research study

1. Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you have been diagnosed with Inflammatory Bowel Disease (IBD) (Crohn's Disease, Ulcerative Colitis, or Indeterminate Colitis). You may also be asked to participate even though you do not have Inflammatory Bowel Disease or surgery.

The plan is to have about 4000 people take part in this study at Mayo Clinic.

2. Why is this research study being done?

The purpose of this research study is to collect clinical information and human samples from patients with IBD. The data collected will be used to create an organized, accessible resource of human samples for biological research in IBD.

3. How long will you be in this research study?

You will be in this study indefinitely, unless you withdraw from the study. You may or may not be contacted again during this time.

4. What will happen to you while you are in this research study?

Your first study visit will take place as part of your regular clinical visit. The physician or clinical research coordinator will go through this consent form with you. If you provide consent and sign the form, the coordinator will perform a questionnaire with you to collect information about your medical history, your experience with IBD, your current and past medication use, and questions about disease activity and general well-being. All future study visits will be at your convenience (example: stool collection) or in association with procedures happening for your clinical care (example: colonoscopy).

You will be asked to:

- Provide a sample of blood (about 6 tablespoons): Your blood contains DNA, which has all of your genetic information. Researchers are especially interested in studying DNA, although many types of studies will be done using the samples in the Biobank. The blood sample may be given at the time of your blood draw at Mayo Clinic. In addition, we may mail you out a blood draw kit to get your blood drawn locally and then mailed back to Mayo Clinic.
- Allow us to keep a part of your tissue to be stored for the study. The tissue may be acquired as biopsies during a colonoscopy or the tissue may be acquired if you are having bowel surgery.
- Medical Records: We access your medical records to verify diagnoses and clinical history. We will examine your medical records for the year prior to your initial study visit and all years following that you are a participant in the study.
- Complete a questionnaire once every 12months. Questionnaire will take about 20 minutes to complete and will ask you about your background, environment and family history.
- Provide a stool sample. A stool sample may help us to understand IBD.
- Provide a urine sample. A urine sample may help us to understand IBD.

In the future:

- We may occasionally ask you to fill out additional questionnaires: We may send additional questionnaires to your home. You can decide if you wish to complete and return them. Research study staff will not contact you more than twice every year (and generally much less), and such contact does not mean that anything has been learned about your health.
- We may ask you to provide additional samples over time. If we ask you for another sample, you may always say no.
- We may ask you if you would like to participate in an addition research study, a sub-study of this research project. If we ask for your participation, you may always say no.

What will happen in this research study?

Blood Collection: For patient under 18 years old, the amount of blood drawn will not exceed 50 ml or 3 ml per kg (of your weight), whichever is the lesser. For non-pregnant adults, who weigh at least 110 pounds, the blood draw amount will be about 6 tablespoons of blood (up to but not exceeding 90ml). Blood samples will be collected no more than 4 times per year, and at least 3 months apart. The blood may be drawn is in addition to blood drawn for any routine purposes that your doctor feels are necessary to care for your underlying IBD. The research blood can be drawn at the same time as your routine blood work so an extra needle stick may not be necessary. Blood draw may also be drawn locally with a mail-out kit. Your research blood will then be stored.

I agree to have a blood sample collected for the study.

☐ Yes ☐ No Please initial here: _____Date: _____

Tissue Collection at time of colonoscopy: If your tissue is collected at colonoscopy, 16 very small pieces (called biopsies) of the lining of your bowels will be removed in addition to those obtained for clinical purposes. Each piece will be about the size of a sesame seed. In all, these pieces will add up to being smaller than a pea.

I permit research biopsies to be collected for the study.

☐ Yes ☐ No Please initial here: _____Date: _____

Tissue Collection at time of surgery: If your tissue is collected at surgery, tissue will be taken from the part of the bowel that was removed during surgery. We are asking if a part of this tissue can be stored for the study.

I agree to have a portion of the tissue to be collected for the study.

☐ Yes ☐ No Please initial here: _____Date: _____

Stool Collection: You may also be asked to provide a stool specimen. Supplies will be given to you to facilitate collection and return of the stool specimen.

I agree to provide a stool sample for this study.

☐ Yes ☐ No Please initial here: _____Date: _____

Urine Collection: You may also be asked to provide a urine specimen. Supplies will be given to you to facilitate collection and return of the urine specimen.

I agree to provide a urine sample for this study.

☐ Yes ☐ No Please initial here: _____Date: _____

Reports about research done with your tissue, blood and stool will not be given to you or your doctor. These reports will not be put in your health record. The research will have no effect on your care.

5. What are the possible risks or discomforts from being in this research study?

This study involves testing your DNA, which is the genetic information you inherited from your parents (also known as genetic testing). If a researcher finds that results from the genetic testing performed on your samples may be useful for your health care, you may be contacted and given the choice to learn the test results. At this time, you will be given general information on the potential risks, benefits, and costs of choosing to learn the test results. The risks of learning genetic test results may include emotional upset, insurance or job discrimination, and/or changes in family relationships because test results may affect other blood relatives. No genetic test results will be put into your medical record unless you choose to learn the results of the testing. Sometimes results should be released only through a genetic counselor who can help explain the possible risks and benefits of learning this information, as well as what these results could mean for you and your family.

Blood Draw: The risks of drawing blood include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick.

Biopsies of the intestine: Biopsies will be obtained during all endoscopy procedures. Bleeding can occur from biopsies, but it is usually minimal and stops quickly or can be controlled. Major bleeding episodes that require blood transfusions or hospitalization are extremely rare.

Procedures: There may be additional risks associated with performing a colonoscopy or surgery. Your doctor will discuss the risks of colonoscopy and bowel resection as these tests and procedures are part of your standard clinical care.

Discomfort with answering a questionnaire: Some questions you will be asked to answer in the study questionnaire(s) may make you feel uncomfortable. You may choose not to answer any questions that make you feel uncomfortable.

Confidentiality: As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

6. Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you don't follow the study procedures,
- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.
We will tell you about any new information that may affect your willingness to stay in the research study.

7. What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

8. What are the possible benefits from being in this research study?

You won't benefit from taking part in this research study. It is for the benefit of research.

Taking part in this research study will not change your rights and benefits. Taking part in this research study does not give you any special privileges. If you decide to not participate in this study, or stop in the middle of the study, no benefits are taken away from you. You do not have to be in this research study to receive or continue to receive medical care from Mayo Clinic.

9. What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

10. What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Blood draws additional to clinical care samples
- Stool collections additional to clinical care samples
- Urine collection
- Additional research biopsies

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care. These tests and procedures are:

- Blood draws ordered by your regular doctor for clinical care
- Stool collections ordered by your regular doctor for clinical care
- Surgery
- Colonoscopy

You will also be responsible for any co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

11. Will you be paid for taking part in this research study?

You won't be paid for taking part in this study.

12. What will happen to your samples?

We would like to keep your sample for future research. You can still take part in this current study even if you don't want your sample used for future research. If you agree to give your sample, it will be the property of Mayo Clinic.

Other researchers at Mayo Clinic who aren't involved with this study may ask to use your sample for future research. Researchers at other institutions may also ask for a part of your sample for future studies. Your sample will be sent to researchers in a coded format, which protects your identity.

Some future studies may examine your DNA, which is the genetic information you inherited from your parents (genetic testing). The Principal Investigator may contact you if there are findings which may be useful for your health care. You would be given general information on the potential risks, benefits, and costs of choosing to learn about the findings.

Please read the following statements and mark your choices:

1. I permit my samples to be stored and used in future research of IBD at Mayo Clinic:

   ☐ Yes ☐ No Please initial here: _____Date: _____

2. I permit my samples to be stored and used in future research at Mayo Clinic to learn about, prevent, or treat any other health problems:

   ☐ Yes ☐ No Please initial here: _____Date: _____

3. I permit Mayo Clinic to give my samples to researchers at other institutions:

   ☐ Yes ☐ No Please initial here: _____Date: _____

There is a very small chance that some commercial value may result from the use of your donated sample. If that happens, you won't be offered a share in any profits.

You may request to have your sample destroyed by writing to the Principal Investigator. The address is found in the "Contact Information" section of this consent form.

Because we cannot predict how your sample will be used in the future, we cannot promise that samples can be retrieved and destroyed.

13. How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. When the information and samples you contribute are analyzed for research purposes, your identity will not be linked to them. Your de-identified clinical information from your interviews and medical record will be linked to your de-identified samples (blood, tissues, stool, and urine). All electronic files are kept on password protected computers. Study regulatory documents and subject consent forms will be stored in a locked cabinet.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

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Who may use or share your health information?

- Mayo Clinic research staff involved in this study.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

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You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission lasts forever, unless you cancel it.

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ENROLLMENT AND PERMISSION SIGNATURES:

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent or receiving via mail

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature