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| Protocol Title:Prospective Registry in IBD Study at Massachusetts General Hospital (PRISM) |
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| Principal Investigator:Ramnik Xavier, MD |
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| Site Principal Investigator: |
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| Description of Subject Population:Multi'omics substudy (Adults recently diagnosed with IBD) |
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# About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called “subjects.” This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as “Partners.”

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

# Why is this research study being done?

The purpose of the PRISM study is to increase understanding about the causes of inflammatory bowel disease (IBD) as well as the factors that may influence the course of IBD over time. IBD is the term used for ulcerative colitis or Crohn’s disease.

This study will look at the genes you have inherited from your ancestors as well as proteins and biological markers that may cause your disease. Investigators are also trying to learn to what extent microbes (such as bacteria) affect disease risk and outcomes. Proteins are the main building blocks of cells. Biological markers are substances that can be measured when taken from the body. Microbes are microscopic organisms that are found in many places, including the gut of human beings. Your genes will help study investigators try to predict the cause of IBD and whether your disease will be mild or severe. Looking at your genes will also help investigators understand how a person with IBD will respond to different medications developed to treat their condition.

**Why have I been asked to take part in the IBD Multi’omics sub-study?**

To test for the different genes and inherited markers, Massachusetts General Hospital will ask a total of 3,600 people to take part in the parent, or main registry called “PRISM”. There will be 3,100 people with Crohn’s disease or ulcerative colitis, and 500 people without Crohn’s disease or ulcerative colitis.

We are asking you to take part in the IBD Multi’omics sub-study within PRISM because your physician believes you may have IBD (either Crohn’s disease or ulcerative colitis). The results of your colonoscopy may help your doctor determine whether or not you have IBD. Only subjects with a diagnosis of Crohn’s disease or ulcerative colitis will qualify. We are asking a total of 24 patients recently diagnosed with IBD to take part in this study.

**How long will I take part in this research study?**

We will ask all subjects to donate research biopsies (tissue samples) during a routine colonoscopy to determine eligibility. If you qualify and agree to participate we will ask you to complete additional stool collections, blood draws, and questionnaires over the course of 12 months. There will be 5 office visits occurring at months 0 (enrollment), 3, 6, 9, and 12.

Additionally, if your doctor schedules you for a follow-up colonoscopy during the 12 months you are participating in this study, you may be asked to donate additional research biopsy samples. This second biopsy collection is optional. You may say “no” and still participate.

**What will happen in this research study?**

**Screening colonoscopy: 60 minutes**

*Research biopsy collection*: If your primary gastroenterologist recommends a colonoscopy or sigmoidoscopy for routine medical care, you will be asked to have biopsies (small pieces of the intestine taken and preserved for examination for various tests) taken from the lining of your colon for study purposes.

Depending on what type of IBD you have, you will have either a colonoscopy or a sigmoidoscopy. If you have Crohn’s disease, a colonoscopy may be done to look at the amount of inflammation in your intestinal tract. A colonoscopy is a test in which a lighted tube is passed through the rectum into the entire bowel (colon) to see if you are having redness or swelling (inflammation). You will receive intravenous medication through a catheter to make you comfortable and sleepy throughout the procedure. If you have ulcerative colitis, a sigmoidoscopy may be done to look at the amount of inflammation in your intestine. A sigmoidoscopy is a test in which a lighted tube is passed through the rectum into the bowel (sigmoid colon) to see if you are having any redness or swelling. Medication to make you comfortable and sleepy is not usually needed, but will be given to you if you request it.

During your procedure you will have biopsies taken for study purposes if you agree to participate. You may or may not have additional biopsies taken for your routine medical care. Each biopsy is around 1/8 of an inch across. If you have IBD or are suspected of having IBD and your intestine shows inflammation (redness, swelling) you will have a colonoscopy or sigmoidoscopy with up to 12 biopsies for study purposes. This is in addition to any biopsies taken for your routine care. If your intestine shows no inflammation, you will have a colonoscopy or sigmoidoscopy with up to 11 biopsies for study purposes, in addition to any biopsies taken for your routine care.

The extra time needed to collect study biopsies is 20 minutes, so the total regular procedure may last 60 minutes instead of 40 minutes.

If something abnormal is found during the colonoscopy or sigmoidoscopy, the results will be given to your primary gastroenterologist, with your permission. Your primary gastroenterologist will then decide how to manage them. If you are diagnosed with IBD following your colonoscopy/ sigmoidoscopy, you will be asked to return to MGH within 2 weeks to complete the baseline visit. If the results of your procedure show that you do not have IBD, you will not qualify to continue participating in this study.

*Stool collection*: At the end of this visit you will be given a stool collection kit to take home and asked to mail a sample to the Broad Institute in 2-3 days.

**Baseline visit (enrollment): 20-60 minutes**

*Interview*: During this visit, a clinical history will be taken, and a list of the medications you are currently taking will be recorded.

*Blood collection*: You will be asked to give approximately 4 teaspoons of blood to test for genetic and biologic markers.

*Questionnaires*: You will be asked to fill out 6 questionnaires. All of your answers to these questionnaires are important to this study and will be kept in the strictest confidence, but you may skip any question you do not feel comfortable answering.

*Abdominal exam*: If you have not been in to the clinic to see a physician in the past month, a study investigator will perform a focused abdominal exam at this visit. The results of this exam will help the investigators rate the severity of your disease.

*Stool collections*: You will be given an additional 5 stool collection kits to take home and asked to collect a sample every 2 weeks until your next office visit.

**Follow-up Study Visits (Months 3, 6, 9, 12): 10-40 minutes**

*Interview*: During this visit, the study coordinator will ask you about changes to your medications and how you have been feeling.

*Blood draw***:** We will collect up to 20mL (about 4 teaspoons) of blood during the follow-up visits.

*Questionnaire*: We will ask you to complete 1 questionnaire.

*Abdominal exam*: A study doctor or nurse will perform a focused abdominal exam which will help the investigators rate the severity of your disease.

*Stool kits*: You will be given 6 new stool collection kits to take home at the month 3, 6, and 9 follow up visits.

**Interim stool collections: 20-30 minutes each**

You will be asked to collect and mail a stool sample every other week for 12 months (24 samples total).

*Activity Index and Dietary Recall***:** On the day you collect each of the 24 stool samples, we will ask you to complete the Activity Index and Dietary Recall and mail it with your sample. We think this questionnaire will take 5-10 minutes.

Shipping supplies, instructions, and mailing labels will be provided.

**Follow up Colonoscopy / Sigmoidoscopy Procedure (OPTIONAL): 60 minutes**

If your primary gastroenterologist recommends a colonoscopy or sigmoidoscopy for routine medical care during the 12 months while you are participating in this research study, you will be asked to have additional biopsies taken for research purposes. This second donation of research biopsies is optional. You can say “no” and still participate in the research study.

During your procedure you will have biopsies taken for study purposes if you agree to participate. You may or may not have additional biopsies taken for your routine medical care. Each biopsy is around 1/8 of an inch across. If you have IBD or are suspected of having IBD and your intestine shows inflammation (redness, swelling) you will have a colonoscopy or sigmoidoscopy with up to 12 biopsies for study purposes. This is in addition to any biopsies taken for your routine care. If your intestine shows no inflammation, you will have a colonoscopy or sigmoidoscopy with up to 11 biopsies for study purposes, in addition to any biopsies taken for your routine care.

The extra time needed to collect study biopsies is 20 minutes, so the total regular procedure may last 60 minutes instead of 40 minutes.

If my physician schedules me for a colonoscopy or sigmoidoscopy during the 12 months I am participating in this study, I agree to donate additional biopsy samples for the research described in this consent:

**Yes\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_ Initials\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

The material obtained from your blood, biopsy, and stool samples will be labeled with a code number and sent to the Broad Institute of MIT and Harvard in Cambridge, MA for analysis. These samples may be stored indefinitely in freezers at the Broad Institute. There will be no information on the sample that will let anyone at the Broad connect this sample with you. The key to the code will be kept in the research office at MGH in a locked file.

Samples may be shared with third parties for future uses related to the study of IBD and other inflammatory diseases.

**Voluntary Participation/Early Withdrawal:**

Your participation in this study is voluntary. You may withdraw your consent at any time and stop participating in this study by notifying the Principal Investigator. You may also ask that any samples being stored for future testing be destroyed when you end your participation in this study by writing a letter to the Principal Investigator stating that you wish all samples be destroyed.

You will not be told any results of the tests done solely for this research, and these test results will never be put in your medical records. You will be notified if anything abnormal is found during your colonoscopy or sigmoidoscopy procedure We will not release the results of specific tests that are done on your samples for the purposes of this study.

By signing this consent form, you give us permission to take and use your blood, stool, and biopsy tissue samples as well as material obtained from the samples, for all of the research described above.

**What are the risks and possible discomforts from being in this research study?**

**Risks from taking biopsies during colonoscopy / sigmoidoscopy procedure**

The risks from taking biopsy samples are extremely low. Among the over 10,000 colonoscopies in which a biopsy was performed over the last seven years at Massachusetts General Hospital, only two medically important problems occurred as a result of the biopsy. One patient experienced bleeding from a biopsy that led to hospitalization. A second patient experienced less than 24 hours of fever and abdominal pain that did not require hospitalization.

**Risks of participating in genetic research**

Possible risks of participating in genetic research include concerns regarding links between your genetic make-up and medication(s) you are currently taking. There may also be concerns about links between your genes relevant to the course or treatment of IBD. Your genes may also reveal risks of other hereditary disease(s). The release of this information to you, your family or third parties could upset you and/or have undesired effects on your ability, or the ability of your family members, to obtain a job or insurance.

To lower this risk, results of genetic studies will not become part of your medical record. Results of genetic studies will also not be shared with subjects. Additionally, results from genetic research will not be released because they are not clinically relevant. All patients will be assigned a random (assigned by chance) subject identification number upon enrollment in the study.

**Discomfort in answering sensitive, personal questions**

You may be uncomfortable answering some of the questions we ask you about your medical history or personal information. Your answers will be kept confidential and will not be associated with your name or personal identifying information. You may choose to not answer any questions that you do not feel comfortable answering.

**Risks of blood drawing**

It is possible you may have some mild pain, swelling, bruising and/or a mild infection at the place where the needle enters the vein when your blood is drawn. If an infection develops, it can be treated. Some people may develop lightheadedness or fainting.

**How will my genetic information and biological samples be used?**

We may also perform a whole genome analysis on your DNA sample.  Usually researchers study just a few areas of your genetic code that are linked to a disease or condition.  In whole genome studies, all or most of your genes are analyzed and used by researchers to study links to many diseases or conditions.

In order to allow researchers to share test results, the National Institutes of Health (NIH) and other central repositories have developed special data (information) banks that analyze data and collect the results of whole genome studies.  These banks may also analyze and store DNA samples, as well.  These central banks will store your genetic information and samples and give them to other researchers to do more studies.  We do not think that there will be further risks to your privacy and confidentiality by sharing your samples and whole genome information with these banks.  However, we cannot predict how genetic information will be used in the future.  The samples and data will be sent with only your code number attached.  Your name or other directly identifiable information will not be given to central banks.  There are many safeguards in place to protect your information and samples while they are stored in repositories and used for research.

Research using your samples and whole genome information is important for the study of virtually all diseases and conditions.  Therefore, the sample/data banks will provide study data for researchers working on any disease.

We may also run a fecal calprotectin test on your stool samples. This test measures mucosal inflammation in human stool to help diagnose ulcerative colitis and Crohn’s disease and to differentiate IBD from other bowel conditions. Stool samples will be analyzed anonymously.

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

We do not anticipate any benefits to you for taking part in this study. However, the information that might be gained from this study might help doctors understand the cause of IBD and how best to treat people with these diseases.

# Can I still get medical care within Partners if I don’t take part in this research study, or if I stop taking part?

Yes. Your decision won’t change the medical care you get within Partners now or in the future. There will be no penalty, and you won’t lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

**What should I do if I want to stop taking part in the study?**

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

It is possible that we will have to ask you to drop out before you finish the study. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

# Will I be paid to take part in this research study?

You will be offered free parking (up to 4 hours) at the Massachusetts General Hospital garage on the day of your appointments. You will be compensated $25 for each of the 24 stool samples you submit for a total of up to $600.00.

**What will I have to pay for if I take part in this research study?**

The tests and procedures that will be done only for the research will be paid for by study funds. The cost of your routine medical care will be billed to you or to your insurance provider in the usual way.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

# If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Dr. Ramnik Xavier, MD is the person in charge of this research study. You can call him at (617) 724-6007 Monday through Friday from 8:00 am to 5:00 pm. He can be reached twenty-four hours a day by calling the MGH page operator at (617) 726-2241 and asking to have Dr. Xavier paged. You can also call the study coordinatorat (617) 726-0698, Monday through Friday from 9:00 am to 5:00 pm, with questions about this research study.

If you have questions about the scheduling of appointments or study visits, please call Robin Wilson at (617) 726-0698.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 617-424-4100.

You can talk to them about:

* Your rights as a research subject
* Your concerns about the research
* A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as “health information.” In general, under federal law, 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.

In this study, we may collect health information about you from:

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

Who may see, use, and share your identifiable health information and why they may need to do so:

* Partners research staff involved in this study
* The sponsor(s) of this study, and the people or groups it hires to help perform this research
* Other researchers and medical centers that are part of this study and their ethics boards
* A group that oversees the data (study information) and safety of this research
* Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
* The Partners ethics board that oversees the research and the Partners research quality improvement programs.
* People from organizations that provide independent accreditation and oversight of hospitals and research
* People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
* 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 US or foreign government bodies that oversee or review research)
* Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
* Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy. However, once your information is shared outside Partners, we cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

Your Privacy Rights

You have the right not to sign this form that allows us to use and share your health information for research; however, if you don’t sign it, you can’t take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

### Statement of Study Doctor or Person Obtaining Consent

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

Study Doctor or Person Obtaining Consent Date/Time

**Statement of Person Giving Informed Consent and Authorization**

* I have read this consent form.
* This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
* I have had the opportunity to ask questions.
* I understand the information given to me.

# Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject Date/Time

Consent Form Version: v.1 October 15, 2013