University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: November 20, 2020
IRB Study # 14-3156
Title of Study: Risk factors for microscopic colitis
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What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary. You may refuse to join, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to investigate risk factors for a condition called microscopic colitis. Microscopic colitis is an increasingly common cause of diarrhea in adults. You are being asked to be in the study because you are about to have a colonoscopy for diarrhea.

Are there any reasons you should not be in this study?
You should not be in this study if you are under age 35 or have a prior history of ulcerative colitis or Crohn's disease.

How many people will take part in this study?
There will be approximately 1200 people in this research study.

How long will your part in this study last?
Your participation in this study will last slightly more than one hour. The blood drawing procedure and height and weight measurements will take 2-5 minutes and the biopsies will add about 5 minutes to your procedure. After your procedure, your biopsies will be read to determine if you are eligible to continue in the study. If you are determined to be ineligible, you will be informed by telephone or email by study staff. If you are deemed eligible for the study, you will be contacted to schedule your study interview. The interview will take about 30 minutes. If you elect to complete the interview online, it will take about 30 minutes. A follow-up survey takes about 10 minutes. Specimens obtained as part of this study will be stored indefinitely.

What will happen if you take part in the study?
During the course of this study, the following may occur:

1. You will be asked to sign an Informed Consent Form, a HIPAA authorization for use of health information for research purposes, and consent for storing biological specimens. You will be given a signed and dated copy of each of these forms and a copy will be placed in your medical record.
2. Your weight, height will be measured. You will be asked to describe your bowel movements before you took the preparation for the colonoscopy.
3. No more than fourteen pinch biopsies of mucosal tissue, each about the size of a piece of rice, will be taken from your colon during colonoscopy for research purposes. These will be taken from first, middle and lower thirds of your colon. This procedure will be performed by the physician performing this colonoscopy scheduled for clinical reasons in addition to the biopsies that will be taken because you have diarrhea. The tissue will be processed to identify bacteria and markers of inflammation. You will also sign a separate consent for future unspecified tests to be performed on the colon tissue.
4. A blood draw of about four tablespoons (five tubes or 40 ml) of blood will be drawn for research purposes. The blood will be drawn through the intravenous line. The blood will be tested for future unspecified tests. You will also sign a separate consent for future unspecified tests to be performed on blood specimen.
5. You will be asked to participate in a computer assisted telephone interview (CATI) that will be conducted at your convenience by a trained research assistant after your colonoscopy. The interview will obtain information about such things as diet, past and present health, and bowel habits. You will be asked to provide verbal consent to the interview. The interview is for research purposes and you may refuse to answer a question for any reason. Alternatively, you have the option of

completing the interview using the Internet. We would email you a unique link to our secure site to access your survey.

What are the possible benefits from being in this study?
Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study?
This study might involve the following risks and/or discomforts to you:

1. The biopsies will be taken through the colonoscope by the physician who performs the colonoscopy; these biopsies are painless. Biopsies are commonly performed during routine colonoscopy. We have obtained thousands of biopsies in previous studies without incident. Except for a small amount of bleeding, the biopsy procedure is generally without risk.
2. You may experience bleeding or bruising at the IV site or blood draw site.
3. There are no known risks associated with answering questions about your diet, or your health or bowel habits.

In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the researchers

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

Access to information obtained from you will be limited to members of the research team. All members of the research team have been trained in the protection of information about human subjects. They have signed a written pledge to maintain the confidentially of study information. Your study records are encoded with a study ID number to ensure privacy and are stored in locked cabinets with controlled access. The link to the study ID is kept in a secure database and access limited to study team members.

Federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most

employers to discriminate against you based on your genetic information. GINA does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination based on an already-diagnosed genetic condition or disease.

What is a Certificate of Confidentiality?

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?

You will receive a gift card for $25 after completing the interview either by telephone or Internet.

Will it cost you anything to be in this study?

It will not cost you anything to be in this study beyond what you will be billed for your routine medical care. All tests, visits or procedures other than what is done for this

study will be related to medical care that is part of the usual care for your condition and would be suggested even if you decided not to be in the research study.

Who is sponsoring this study?

Funds for this study come from the National Institutes of Health (NIH). This means that the research team is being paid by the NIH for doing the study. The researchers do not, however, have a direct financial interest with the sponsor in the final results of the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study and I consent to (please initial on each line as appropriate):

_____ Blood sample

_____ Tissue biopsies

_____ Surveys

_____ _____

Signature of Research Participant Date

_____

Printed Name of Research Participant

_____ _____

Signature of Research Team Member Obtaining Consent Date

_____

Printed Name of Research Team Member Obtaining Consent