Broccoli Sprouts for Mild Ulcerative Colitis

NCT05507931

Actual Date of IRB Approval: August 15, 2024

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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.

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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**.**

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Study ID: HUM00210637 / Continuing Review ID: CR00113491

Approval Date: 1/15/2026

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UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Broccoli Sprouts for Mild Ulcerative Colitis- HUM00210637

Company or agency sponsoring the study: United States Department of Agriculture (USDA)

Principal Investigator: Grace Chen, MD, Department of Internal Medicine

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This is a pilot study to look at the effects of eating broccoli sprouts daily for one month. The study involves a process called randomization. This means that the amount of broccoli sprouts you are assigned to eat for this study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare the effects of different servings of broccoli sprouts. As this is an early investigation, it is not known whether broccoli sprouts will benefit people with ulcerative colitis (UC).

Your protected health information, blood, stool, and information about your dietary habits will be collected for this research study.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, some of these risks may include increased gas or bloating from eating broccoli sprouts, potential loss of confidentiality, and pain or redness at the site of blood draw. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future by helping researchers learn more about broccoli sprouts as a potential dietary therapy to manage your ulcerative colitis. Although results cannot be guaranteed and there is limited information related to the outcomes of inflammatory bowel disease (IBD) patients who eat broccoli sprouts, it is our hope that this diet will help improve your ulcerative colitis. This study may also benefit patients in the future with this disease.

We expect the amount of time you will participate in the study will be approximately 2 months.

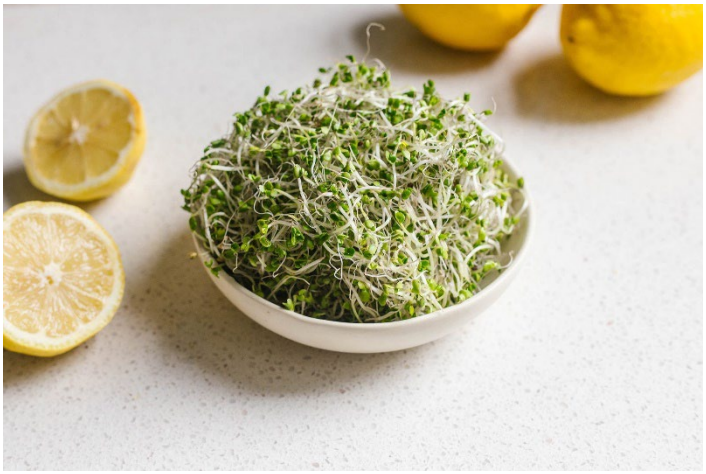
You can decide not to be in this study. An alternative to joining this study would be to continue following the medical advice from your gastroenterologist.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

2. PURPOSE OF THIS STUDY

2.1 Study purpose: The goal of this study is to find out:

- whether 1 or 3 servings of broccoli sprouts a day is enough to increase blood and stool levels of sulforaphane, a natural plant compound found in certain vegetables known as cruciferous vegetables (for example, arugula, bok choy, broccoli, broccoli rabe, brussels sprouts, cabbage, cauliflower, Chinese cabbage (napa), collard greens, horseradish, kale, radishes, rutabaga, kohlrabi, mustard greens, turnips, watercress, and wasabi) that has anti-oxidant and anti-inflammatory properties.
- whether a broccoli sprouts diet can reduce inflammation in the intestine.
- what effects broccoli sprouts have on the bacterial populations in your intestine.
- How easy or difficult it is to eat the assigned number of servings of broccoli sprouts daily.



Broccoli Sprouts

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. 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?
You are being asked to take part in a diet research study because you have been diagnosed with mild ulcerative colitis.

Every study has strict guidelines for determining which people may participate. These are called eligibility criteria. You will need to meet all of these criteria before you can participate in this study. If you agree to consider participating in this study, you will undergo evaluations to see if you meet the eligibility criteria for this study.

Inclusion Criteria:

- Male or female 18 years or older.
- Diagnosis of mild ulcerative colitis
- Currently being treated with a stable dose of 5-ASAs, steroids, or any other medication approved for Ulcerative Colitis:
    - If on 5-ASA, no dose changes within 2 weeks before the Day 0 visit
    - If on steroids, prednisone dose not more than 20 mg daily and entocort not more than 9 mg daily, with no dose changes within 2 weeks before the Day 0 visit
    - All other medications require a stable dose for at least 8 weeks prior to enrollment. No dose changes to any IBD medication anticipated for the duration of the study
- Your Body mass index (BMI) is between 18.5-40 kg/m^2.
- You are able to understand the study procedures, benefits and risks of study, and sign a written informed consent document.
- You are able to fill out questionnaires regarding your diet, bowel symptoms, and experience with the study.

Exclusion Criteria:

- You follow a medically-prescribed diet, are on TPN, or receive tube feeds.
- You have newly diagnosed (within past month), or uncontrolled diabetes or cardiovascular disease.
- You have taken antibiotics in the previous 2 weeks.
- Your dose of 5-ASA has changed within the past 2 weeks.
- You eat more than 5 ½ cups of servings/day of fruits and vegetables based on the National Cancer Institute Diet History Questionnaire III (NCI DHQ3).
- You have a known allergy or sensitivity to cruciferous vegetables like arugula, bok choy, broccoli, cabbage, cauliflower, or collard greens

3.2 How many people are expected to take part in this study?
We are planning to enroll 40 subjects from the University of Michigan. 20 subjects will be randomized to receive 1 serving of broccoli sprouts per day, while the remaining 20 subjects will receive 3 servings per day. You will remain on your usual prescribed medications for UC throughout this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

Randomization and Treatment Plan:

If you are eligible to join the study and agree to be in the study, you will be randomly assigned to either one (4 oz or 113 g) or three (12 oz or 339 g) servings of broccoli sprouts daily for 28 days. Subjects will be assigned to groups randomly in a manner that ensures similar ages and numbers of males and females in each group. After the assessments at the Day 0 visit are completed, you will be informed of your assigned diet.

Assessments:

- A baseline health status questionnaire will capture your demographics, medications, health history and current health status. At study end, your current health status will be asked again
- You will be given a diet log to help keep track of the amount of broccoli sprouts you eat and the amount of non-study cruciferous vegetables (e.g., cauliflower, kale, cabbage, brussels sprouts, and more – see diet log for a complete list).
- Medical history will be obtained from your medical chart and self-reported in the study questionnaires.
- You will also be asked to complete the NCI DHQ3 questionnaire online at home at time of screening before the baseline visit (example here - https://epi.grants.cancer.gov/dhq3/). This initial diet questionnaire will allow us to assess your baseline diet.
    - At the end of the study, we will provide you a nutritional assessment generated from this questionnaire. If you have any significant nutritional deficits, you will be provided with a list of foods rich in the nutrients your diet lacks, and a referral to a dietitian.
- You will complete a cruciferous food frequency questionnaire (ACV FFQ) before and after starting the broccoli sprouts diet. We will use a set of measuring cups as a visual guide to help you estimate portion sizes.
- Height, weight, waist, and hip measurements at baseline (Day 0) and at end of study (~Day 28)
- Blood (up to 1.3 tablespoons, or 20 mLs) will be taken on Day 0 and at end of study (~Day 28) to measure levels of sulforaphane, other plant metabolites, and inflammation
- Stool will be collected to measure levels of sulforaphane, other plant metabolites and bacterial populations. Stool will be collected with stool collection kits that will be shipped or brought to you at a scheduled study visit.
- An IBD-control questionnaire on Day 0 and Day 28 will be used to assess your ulcerative colitis symptoms have changed.
- An end-of-study questionnaire will be used to evaluate your study experience and whether you were able to eat your assigned number of servings of broccoli sprouts daily.

You will be provided up to a week's worth of broccoli sprouts at baseline visit depending on the amount of refrigerator storage space you have. Subsequently, up to a week's worth of broccoli sprouts will be shipped to your home. You will be given instructions on how to prepare the steamed (for 10 minutes) broccoli sprouts as well as sample recipes. Besides removing bacterial contamination, steaming can reduce the strong taste associated with broccoli sprouts and also reduce its volume, making it easier to eat full servings. It is important you do not microwave the sprouts. You will also be a provided a list of cruciferous vegetables and asked to limit the amount of cruciferous vegetables and condiments to no more than two servings per week starting at least two weeks prior to the Day 0 visit and while on study.

You will be phoned on day 3 to assess any adverse events (negative changes to your health) and difficulties with completing study activities, and answer questions to promote completing these study activities. Adverse events and completion of study activities will be assessed with weekly by phone each week thereafter and at end of study. You will also be asked to save a portion of three different servings

of broccoli sprouts for analysis of plant metabolites, which will be delivered to Dr. Grace Chen's laboratory.

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all of your scheduled appointments, eat the correct amount of servings of broccoli sprouts, and report any adverse reactions you may have during the study.

Study Schedule:

Task	Screening (Day -14[c])	Day 0	Day 3[a]	Day 7[a]	Day 14[b]	Day 21[b]	Day 28/PD[c,d]
Consent	X						
DHQ3	X						X
ACV FFQ		X					X
Randomization		X					
Health Status Questionnaire		X					X
Stool sample		X					X
Blood collection		X					X
Weight		X					X
Height		X					X
Waist and Hip Measurement		X					X
Telephone call			X	X	X	X	
Broccoli sprouts collection							
IBD-Control questionnaire		X					X
End of study questionnaires							X

[a] +/-1 day, [b] +/-3 days, [c] +/-5 days, [d] The Premature Discontinuation (PD) visit may happen any time after Day 0, remotely or in person. All activities for the PD visit are optional.

Optional Crossover from Three-Serving to One-Serving Group

Some people assigned to the three-serving group may find it difficult to eat the full volume of sprouts assigned to them. If you are assigned to the three serving group and are having difficulty eating your assigned portion, please reach out to the study coordinator (contact info in Section 10). We will discuss your concerns and decide together whether to switch to the one-serving group or discontinue study participation.

Optional Future Research

Besides the information about the main study, the following information is specific to unspecified future use of identifiable data and/or biospecimens. We would also like your permission to keep some of your blood, stool and medical information collected in the main study, so that we may study it in future research. The future research may be similar to this study or may be completely different.

You can take part in the main study even if you decide not to let us keep your blood, stool and medical information for future research.

If you give us your permission, we will use your blood, stool and medical information for future research. Even if you give us permission now to keep some of your blood, stool and medical information, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your blood and stool, we may not be able to take the information out of our research.

We may share your blood, stool and medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your specimens and medical information with other researchers, we will not be able to get it back.

Future use of your identifiable data and/or specimens will be conducted in compliance with applicable regulatory requirements.

You will not find out the results of future research on your blood and stool. Allowing us to do future research on your specimens and medical information will not benefit you directly.

With appropriate permissions, your samples and collected information may also be shared with other researchers here, around the world, and with companies. Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

4.2 How much of my time will be needed to take part in this study?
You will be eating broccoli sprouts from Day 0 to Day 28. The two on-site visits (day 0 and day 28) are expected to take approximately 1 hour. Each individual questionnaire can take approximately 15 to 45 minutes to complete. Each phone call will last about 15 minutes.

4.3 When will my participation in the study be over?
Your participation will be over after the Day 28 office visit unless you cancel your participation earlier.

4.4 What will happen with my information and/or biospecimens used in this study?
With appropriate permissions, your biospecimens and collected information may also be shared with other researchers, here, around the world, and with companies. Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY 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:

- Ingestion of steamed broccoli sprouts may cause diarrhea, nausea, bloating, gas, belching and stomach discomfort.

- Steamed broccoli sprouts may cause an oral allergic reaction, including itching, tingling, or soreness of the mouth and throat and nasal congestion.
- You may also experience pain, redness or bruising at the blood draw site.
- Potential loss of confidentiality or privacy, which we feel is unlikely, as we will take multiple measures to protect confidentiality of study records

The researchers will try to minimize these risks by:

- Keeping patient information on secure servers that are password-protected, and electronic communication of information will be encrypted.
- Keeping paper forms with patient identifiers secure in a double lock system
- Labeling samples will with a unique identifier to protect confidentiality, and only members of the study team will have access to patient data.
- Having only trained phlebotomists following best practices draw blood.

See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 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, others may benefit from the knowledge gained from this study.
You may also benefit from participation in this study if eating broccoli sprouts reduces any of your IBD symptoms or promotes healthy eating habits.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
There may be other ways to treat your ulcerative colitis. Your doctor can tell you more about these other treatments, their risks and their possible benefits. You should have this discussion about the risks and benefits or other alternatives prior to making your decision about whether or not you wish to take part in this research study.

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".

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

No. Should you wish to leave the study prior to completing it, we ask that you let us know, and schedule a final office visit to complete surveys, a blood draw and stool sample.

7.3 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:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- 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?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

If you are injured or in the event of a medical emergency, dial 911 or visit your nearest Emergency Room. If you believe the study has made you sick or caused you injury, contact one of the people listed in section 10 of this document (Contact Information). If taking part in the study makes you sick or causes you injury, you or your insurance provider will be billed for all costs of treatment as the study does not provide compensation for sickness or injury caused by the study. It is possible that your insurance will not cover these costs.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

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?

You will receive $50 for completing the Day 0 office visit and providing stool and blood samples, and an additional $50 for the Day 28 office visit, stool and blood samples, for a total of $100 if you complete both study visits and provide stool and blood samples for both visits.

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

The company whose product is being studied: No
The researchers conducting the study: No
The University of Michigan: No

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
Your research information will be stored in a locked cabinet and will not be made a part of your regular medical record. However, if the researcher orders any tests, the order and results may become part of your regular medical record.

9.2 What protected health information (PHI) 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 information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Demographic information
- Personal identifiers

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 the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects

    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, Social Security number, payment amount, and related information for tax reporting purposes.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

A description of this clinical trial will be available on https://www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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 to use my PHI?

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

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

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 a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Grace Chen, MD
Mailing Address: 1500 E. Medical Center Dr, Ann Arbor, MI 48109
Hospital Operator: 734-936-4000

- For urgent, after-hours concerns, call and ask the operator to page Dr. Grace Chen at 13459

Study Coordinator Telephone: 734-764-0507
Study Coordinator Email Address: higginsscteam@umich.edu

- For non-urgent concerns or questions, reach out to the study coordinator by phone or email

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
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?
You will receive a copy of this consent form once all signatures have been obtained.

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Consent/Assent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [name of study team member obtaining consent] _____. My questions so far have been answered. 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 I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Consent/Assent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable specimens/data for use in future research. I understand that it is my choice whether or not to allow future use of my specimens. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the study team keep my specimens for future research.

_____ No, I do not agree to let the study team keep my specimens for future research.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____