UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: MyBestGI Study

Company or agency sponsoring the study:
National Cancer Institute, NIH

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigators:
Zora Djuric, Ph.D., Department of Family Medicine, University of Michigan
Lorraine Buis, Ph.D., Department of Family Medicine, University of Michigan

1.1 Key Study Information

You may be eligible to take part in this 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 your doctor 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.

The MyBestGI Study seeks to evaluate three different methods that could be used for achieving and maintaining an eating style that is thought to reduce the chances of developing colon or rectal cancer. The study therefore seeks to recruit individuals who have had polyps or colorectal cancer in the past or who have a strong family history of colorectal cancers.

The study involves a process called randomization. This means the eating plan that you are asked to follow while in the study is not chosen by you or the researcher. The study is designed to compare three different eating plans over 12 months. The eating plans are: 1) MyBestGI Eating Plan 1; 2) the MyBestGI Eating Plan 2; and 3) the MyBestGI Eating Plan 3. Which eating plan you receive is based on chance, like the flip of a coin.

There can be risks associated with joining any research study. These risks may impact whether you decide to join the study. For this study, there is a blood draw from your arm at 0, 6 and 12 months. There is a slight risk of bruising or infection, or fainting, from this blood draw. In addition, it might be difficult or costly for you to make changes in your diet.

This study may offer some benefit to you now or to others in the future by developing a new way that helps people who have risk factors for colorectal cancer eat a better diet.

We expect the amount of time you will participate in the study will be 12 months.

You can decide not to be in this study. Alternatives to joining this study include finding out about preventive foods and eating styles on your own or working with a dietitian.

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

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

This study conducts research on the prevention of colorectal cancer, the third most common cancer in the U.S. Colorectal cancer is one of the cancers most strongly affected by diet. Despite the research that supports the role of diet in prevention, this has had little impact on the medical care of individuals who are at increased risk of cancer. The three eating plans being tested in this study all focus on improving food choices consistent with the recommendations for cancer prevention, and this might result in some weight loss over time. These methods would be simple to administer in medical settings with minimal in-person support. If successful, the researchers hope that one or more of the three methods will be utilized more broadly in the future as part of usual, preventive medical care.

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?

This study is enrolling people ages 19 and older who agree to participate and come to study visits four times, namely today (enrollment), study start (Visit 2 or study baseline), 6 months (Visit 3) and 12 months (Visit 4).

Eligible people must have a smart phone with a data plan. This is because two of the eating plans involve use of a web-based app.

In addition, eligible people must have one risk factor for colon or rectal cancers as defined by:

- A history of adenomas (adenomatous polyps) in the colon or rectum,
- A known genetic condition that increases risk of colon or rectal cancers,
- Having had colon or rectal cancer in the past that is not far advanced (Stage 1 to Stage 3A), and finished any chemotherapy or radiation therapy more than 12 months ago
- A history of colon or rectal cancers in one primary relative (parent, sibling) or in two secondary relatives (aunt, uncle, grandparent, half-sibling, niece, nephew)

Eligible people need to:

- Have a body mass index (BMI) below 45 kg/m^2 and at least 25 kg/m^2, OR a waist circumference that is at least 88 cm for women or at least 102 cm for men.
- Able to follow an eating plan that includes high fiber foods
- Able to provide accurate reports of foods that they eat
- Have reasonable control over their own diets
- Not expecting major lifestyle changes in the next 12 months
- Willing to follow up with their own physician for conditions or any medication use that could be affected by a change in dietary intakes (such as use of medications for diabetes and high blood pressure)

The following conditions would make people not eligible for the study:

- Pregnant or lactating, or planning to get pregnant
- Have a known infectious disease such as HIV/AIDS or Hepatitis B or C at the present time
- Have any diseases or conditions that would interfere with being able to follow a preventive eating plan or complete study visits
- Had bariatric surgery within the past 12 months
- Have cancer at the present time

3.2 How many people are expected to take part in this study?

The researchers plan to enroll 240 study participants at the University of Michigan, Ann Arbor, MI.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

- Eligibility Testing
  - Diet Questionnaires
  - Eligibility questionnaire
  - Weight and height, waist circumference

- Study Visits at 0, 6 and 12 months
    - Fast overnight for at least 10 hours. Exceptions may be made if you cannot fast that long for medical reasons (for example, diabetes). No exercise or caffeine in the 10 hours before the visit. No alcohol in the 24 hours before. Drink 1 cup (8 oz.) of water 1 hour before the study visit start time. After the testing you will be given a snack and a beverage.
    - Have 2-4 tubes of blood drawn from your arm, less than one ounce total (about 1½ tablespoons or less than 3/4 of an ounce for all tubes combined at each visit).
    - Diet Questionnaires, some of which are done online at home before the visit.
    - Other Questionnaires on your nutrition goals, sleep, stress, physical activity, medical history, technology use and opinions regarding study participation
    - Veggie Meter test. For this test, you will wash your hands and place one finger in the meter. An ordinary white light will shine on your finger and the reflectance will be used to measure compounds found in fruits and vegetables. You will receive the results of this test.
    - Breath Ketone Test. For this test, you will be provided with instructions on how to breathe into the hand-held device. Breath ketones are substances that are produced when people metabolize fats, and this happens when people lose weight. You will receive the results of this test.
    - Weight, height, waist and hip circumferences.
    - Body fat and body lean measures using bioimpedance analysis. You will stand on the instrument with bare feet and hold on to the handles. A small bioelectrical current that people cannot detect will be sent through the metal surfaces. The device will provide a measurement of your body water, lean mass, and fat mass.
    - Randomization to one of three different Eating Plans. You have an equal chance (one-in-three chance) to receive one of the three eating plans.

As a study participant, you have the responsibility to come to your scheduled study visits and to report any adverse reactions you may have during the study.

We will collect and store information about your genetic make-up that is related to metabolism of nutrients and how our bodies react to nutrients. The DNA contained in your genes holds the instructions that your body uses to function. Variations in certain genes can determine how you metabolize nutrients from foods and how you respond to nutrients. These variations in genes are inherited or happen later on. For example, a person who has low levels of cholesterol due to their own, inherited genetic make-up might not have as big a change in blood cholesterol after changing their diet as compared with someone who has high levels of cholesterol to start with. Since we are only looking at specific genes, this information is much more limited than tests that are used to identify people and their families. We will not analyze all of your genes or your entire genome.

We will submit your de-identified genetic information to a repository to be used for scientific purposes. De-identified means that that information is stripped of your name or any other information that could be used to identify you. A scientific repository contains information from many people. Some repositories are maintained by the University of Michigan, some are maintained by the federal government, and some are maintained by private companies. Researchers all over the world can take information from the repository and use it in their studies. Their studies may be similar to this one or may be completely different.

We would also like your permission to keep some of your de-identified blood samples and information collected in the MyBestGI Study for future research done by us or other researchers without additional informed consent. The future research may be similar to this study or may be completely different. Even if you give us permission now to keep some of your blood samples and study information now, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your blood samples and study, we may not be able to take the information out of our research publications.

Future use of your de-identifiable data and/or specimens will be conducted in compliance with applicable regulatory requirements. To de-identify the data and specimens, your identifiable private information will be stripped of any identifiers such as name, address or phone number that could be used to identify you. You can take part in the main study even if you decide not to let us keep your blood samples and study information for future research.

Research can lead to new discoveries, such as new tests, drugs, or devices in the future. 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?

The study lasts 12 months. There are 4 study visits: screening and enrollment (today's visit), study start (Visit 2), 6 months (Visit 3) and 12 months (Visit 4) at study end. The study visits will take about 1-2 hours.

If you receive either Eating Plan 2 or 3, you will also receive brief telephone support calls 10 times over 12 months (about 15-20 minutes per call at weeks 1, 2, 4, 8, 12, 16, 24, 32, 40 and 48). This call will be recorded, if you agree, for training purposes, and it will be transcribed without your identifying information for research investigations aimed at improving the calls. Text messages will be sent to your phone reminding you to log foods eaten and twice a week you will get messages related to the "why and how" of healthy eating. Shopping for food and, if you receive the MyBestGI app, recording what you eat, also will take some time, especially at first when you are learning about how to follow the eating plan. These Eating Plans ask you to log the amount you ate from each food group 3 days/week for the first 12 weeks and 3 days every other

week after during weeks 13-52. This is expected to take a few minutes for each meal on the days that you record food groups.

It is difficult to estimate how much time all these tasks will take, and it may vary for each person.

4.3 When will my participation in the study be over?

The study is designed to last 12 months for each study participant. If you decide to stop before 12 months, you can. After your study participation ends, you may not have access to the study materials or the study materials or app.

4.4 What will happen with my information and/or biospecimens used in this study?

The data and samples collected for this study will be analyzed to identify which Eating Plan results in the best dietary changes. The data and samples will also be used to better understand how diet affects metabolism related to weight change, body mass index and cancer risk.

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 risks of study participation are rare due to the procedures we have in place to minimize these risks. Known risks of study participation are:

1) Breach of confidentiality.
2) Risks of discomfort, infection, bruising, or fainting due to venipuncture
3) Risk from bioelectric impedance analysis measures.
4) Costs of purchasing healthy foods
5) Stress associated with being asked to make dietary changes, to use the app, to make time to set dietary goals
6) Gastro-intestinal issues with following the intervention diets.
7) Costs associated with data usage for using the app (such as increased cellular data usage and maintaining a cellular plan throughout the study) or for home internet usage if you decide to use a computer to access the study app.
8) Frustration with technological issues in using the app.

The researchers will try to minimize these risks by:

1) Confidentiality. To minimize the risk of loss of privacy, all study team members will be trained in privacy, confidentiality, and security measures including the University's online training in ethics ("Program for Education & Evaluation in Responsible Research and Scholarship", PEERRS) and Michigan Medicine HIPAA training. Contacting subjects will be

done with privacy in mind and telephone messages will not be left without permission of the participant. All materials obtained from research subjects will be coded by a subject identifier number and will not contain information that can be used to identify individuals.
To minimize the possibility of loss of data or breach of data confidentiality, data will be stored only on secure Michigan Medicine servers or authorized cloud spaces that require two-factor authentication for access, and back-up is provided nightly. Paper copies of any study documents will be kept in a locked file cabinet in a study research office that is locked when vacant, and the building is locked after normal business hours.

2) Venipuncture. Any discomfort is expected to be minor and infrequent. To minimize risk of bruising or infection from venipuncture, blood will be drawn by trained phlebotomists.

3) Risks from bioelectric impedance measures of body fat and lean. There are no known risks from the very small voltage that is used to measure body composition. Persons with an implanted defibrillator, pacemaker or other electric device should, however, avoid this measure and will not be asked to complete this measure.

4) Costs of food. Participants may encounter costs of purchasing the recommended foods. This is minimized by swapping foods, such as whole wheat bread for white bread, and brown rice for white rice that are generally fairly comparable in price. Buying food at discount grocers is another option for keeping costs reasonable.

5) Stress of study participation. To minimize risk of stress, you will be encouraged to set your own, achievable eating goals. If the study is unduly stressful you may need to stop participating and/or see a doctor.

6) Gastro-intestinal problems. It is possible that eating foods with more fiber could cause discomfort. Starting slowly and building up gradually can help, or you might need to modify your goals. These issues need to be reported to study staff to determine whether or not something can be done or if you should stop participating in the study.

7) If you are randomly assigned to one of the eating plans that involves using an app, costs associated with app use such as increased cellular data usage. However, the data used for the MyBestGI app is expected to be minimal versus that for other ordinary uses.

8) If you are randomly assigned to one of the eating plans that involves using an app, you may be frustrated with technological issues in using the app. Study staff will be available via phone, email, or in-person to handle any technical issues you are having.

The study does collect your dietary data. If any nutritional intakes below 67% of the Recommended Dietary Allowance for micro and macronutrients are identified from the average of three 24-hour recalls, you will be given written information on which foods can be used to

correct that deficiency. Any severe nutritional deficiencies uncovered will need to be discussed and may include referral to a dietitian and/or discontinuation of study participation.

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. 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. The eating plans recommended by the study materials, however, are thought to be healthy. Others may benefit from the knowledge gained from this study in that a new method for helping people choose healthy foods could be developed.

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?

You can always seek out information on healthy foods and how to eat healthy foods on your own. There are also other apps and companies that help people eat healthier.

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?

There is no harm expected to you if you decide to leave the study early.

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 cancelled.

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 that are part of the study visits. The study does not involve nor provide any medical treatments.

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?

If you fully complete all study visits and activities, you will receive a total of $175, paid via checks mailed to your home for the following:

Visit 1 (Enrollment)	$10
Visit 2 (Study start)	$55
Visit 3 (6 months)	$55
Visit 4 (12 months)	$55

If you attend the visits but are unable to complete all of the activities in any one of the visits, you will instead receive the following amounts for the activities you have completed during a partially completed study visit:

Travel to visit	$5
Completing questionnaires at the Enrollment Visit	$5
Completing questionnaires for Visits 2, 3 and 4	$15
Blood draw	$15
Visit 2, 3 or 4 Breath test, Veggie meter test, and body measurements	$20

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

The researchers conducting the study: This research could identify a new method to help people eat healthier. In the future, the researchers could refine this method and create a commercial product. 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

The information below describes how the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my information?

- Note that if you tell us or we learn something that makes us believe that you or others have been or may be harmed, we may be required to report that information to the appropriate agencies.
- Research records will be stored in secure, access-restricted systems, with researchers only accessing your information on an as-needed basis.
- When the data for this study are used for statistical analyses, we will only use a study code to identify you. When the data is stored for future use, all identifying information and codes will be removed so that there is no way to link information back to you.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else

who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the SPONSOR which is funding this project 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 from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others].

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document.

The Federal 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. This law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Under this law:

- Health insurance companies and group health plans may not request your genetic information that we obtain from this research
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums
- Employers with 15 or more employees may not use your genetic information that we obtain from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment

GINA does not apply to the following groups; however, these groups have policies in place that provide similar protections against discrimination:

- Members of the U.S. Military receiving care through Tricare
- Veterans receiving care through the Veteran's Administration (VA)
- The Indian Health Service
- Federal employees receiving care through the Federal Employees Health Benefits Plans

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Information you enter on the ASA24 website for the dietary recall is governed by the information on confidentiality provided on the ASA24 website at https://epi.grants.cancer.gov/asa24/respondent/confidentiality.html.

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.

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, 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.

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: Dr. Zora Djuric
Mailing Address: 1018 Fuller Street, Ann Arbor, MI 48109
Telephone: 734-936-4494

Study Coordinators: Rob Adwere-Boamah or Juno Orr
Mailing Address: 1018 Fuller Street, Ann Arbor, MI 48109
Telephone: (734) 232-4971

Email: MyBestGIstudy@umich.edu

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
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

What documents will be given to me?

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

This "Consent to be Part of a Research Study" document.
Other: Instructions for completing the Automated Self-Administered, 24-hour dietary recall (ASA-24) online and the Baseline Visit Preparation instructions

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

Sig-A

Consent 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/yyyy): _____

Sig-B

Consent/Assent to audio recording solely for purposes of this research
This study involves audio recording. If you do not agree to be recorded, you can still take part in the study.

_____ Yes, I agree to be audio recorded.

_____ No, I do not agree to be audio recorded.

Print Legal Name:_____

Signature:_____

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

Sig-D

Consent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your de-identified specimens/data for use in future research. I understand that it is my choice whether or not to allow future use of my data/specimens. I understand that if my ability to consent 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/yyyy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant with information about this study that I believe to be accurate and complete. The participant 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/yyyy): _____