Informed Consent Form

TITLE: Fiber-rich Foods to Treat Obesity and Prevent Colon Cancer

NCT NUMBER: NCT04780477

IRB APPROVAL DATE: February 27, 2024

You Are Being Asked to Be in a Research Study
Diet, Weight and Colon Cancer Risk

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of approximately 120 people studied at Emory.

Why is this study being done?
This study is being done to answer the question of whether diet composition (e.g., a high-fiber diet rich in legumes or dried beans) affects your weight and your risk of developing colon cancer.

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care related to the conditions being studied - your weight or your colon function. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, your active participation will last for one year. During the year you will be asked to follow one of two dietary patterns (healthy American or high fiber diet) and follow guidelines designed to encourage weight loss. You will also be asked to make a number of visits to the Clinical & Translational Research Center (GCRC) located at the Emory University Hospital on the Emory campus. The researchers will ask you to do the following: provide blood (3 times), urine (3 times) or stool samples (monthly or 12 times), undergo a DXA study to measure body fat, muscle and bone mineral content (3 times), and have small tissue samples (biopsies) taken by scraping the lining of your intestine (3 times). There is also an extended follow-up study that is optional. All of these procedures are described in greater detail below. All of these procedures will be paid for by the study.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question, “Can a high fiber diet based on legumes help to lose weight and reduce colon cancer risk?”

What are the risks or discomforts I should know about before making a decision?
The study will take time. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include the rare but possible risk of infection when we draw blood, the risk of bleeding associated with biopsy (less than 1% or less than 1 in 100 people). Loss of privacy and breach of confidentiality are also possible risks. A full list of expected risks, their frequency and severity are in the “What are the possible risks and discomforts?” section of this document.

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate.

Costs
You will not have to pay for any of the study procedures. The study will provide some funds to support your participation. There is more information in the cost section of this document.

What Should I Do Next?

Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.) Make sure you understand. Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: Fiber-rich Foods to Treat Obesity and Prevent Colon Cancer

Principal Investigator: Terry Hartman, PhD, MPH, RD
Professor of Epidemiology
Rollins School of Public Health, Emory University

Sponsor: National Cancer Institute (primary)

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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.

What is the purpose of this study?

The purpose of this study is to evaluate the effect of a high fiber diet based on legumes (dried beans) on weight loss and on risk for colon cancer.

What will I be asked to do?

If you agree to participate in this study, your active participation will last for approximately one year. You will be randomly assigned to either Legume diet (high fiber featuring legumes) or Control diet (healthy American) by a computer program. You have a 50/50 chance of ending up in either group. The study coordinator will know which one you receive, but the investigators will not know which one you receive. You will be provided your main entrée for both lunch and dinner during the first 3 months you are participating in the study. During months 4-6 you will be provided one entrée per day and you may decide when to consume it. These entrées

will have to be picked up weekly. If you are assigned to the Legume diet group, your meals will include approximately ¾ cup of cooked legumes, such as pinto, black and navy beans, or lentils. If you are assigned to the Control diet group, your entrées will be healthy, typical American foods (without legumes). Both groups will be able to eat additional foods and snacks, preferably from our recommended healthy foods list. Both groups will receive weight loss guidance from the study staff. The study staff will provide guidance to assist you in making healthy food choices so that you should gradually lose weight over 6 months. During the next 6 months of the year (months 7-12) you are encouraged to continue to follow a diet similar to your assigned study diet on your own and to maintain your weight loss and/or to continue to gradually lose weight. The study will provide you with a health coach to consult with during your one year of active participation.

Screening Procedures
We will screen you to find out if you can be in the study. We will conduct a phone interview to determine your initial eligibility. If you wish to participate in this study, you will also need to undergo a screening evaluation at the GCRC at Emory University. During this visit, after giving your consent (this document), you will have your height and weight checked by clinic staff, you will be asked some questions related to your health status, and if you are eligible for the study, instructions for the week prior to your baseline visit (run-in diet week) will be given. We will also estimate your daily calorie needs.

Baseline Week Prior to Randomization
The week prior to being randomized to a particular diet group, we will provide your main dishes for both lunch and dinner and we will ask you to participate in 2 phone or video calls to determine the foods eaten during the past 24 hours. These calls will take approximately 30 minutes each. There will be a short questionnaire related to your usual (e.g., frequency) and recent (e.g, recent travel or illness) bowel habits. We will also ask you to collect a stool sample for gut microbiome analysis. You will be instructed in the use of a plastic device to cover the toilet seat and collect the stool. You will be asked to bring the sample to the clinic. You may wish to collect this sample on the day that you will be returning to the GCRC at Emory for your Randomization and Baseline visit.

Randomization and Baseline Visit
On the day of randomization, you will be asked to return to the GCRC at Emory University for baseline lab testing, a biopsy procedure, and randomization. This visit will begin early in the morning and take several hours. You will have your height, weight and waist circumference measured by the study staff or nurses at the clinic.

These tests and procedures will be done as part of the study:

1) Questionnaire data: We will collect demographic data (e.g., age, sex, race, education) and information about your usual physical activity, sleep habits, smoking and alcohol use. We will also ask you about your bowel habits and any food allergies that you may have.
2) Urine sample: We will also ask you to collect a urine sample for metabolomics analysis. We will provide instructions and collection materials for the urine sample.
3) Fasting blood draw: A fasting blood sample (approximately 35 ml) will also be taken to determine your CRP (a marker of inflammation), glucose and insulin and fatty acid levels. The blood samples will be stored for analysis at a future date. The analysis done on your blood for this study will be restricted to those that influence how the body manages inflammation, how body weight changes, how the body

uses energy or hormones, or related to your bowel health or risk for colon cancer. Should you withdraw from the study, we will keep your blood for analysis unless you notify us in writing that you do not want this.

4) DXA study: a DXA study will be done to measure body fat, muscle and bone mineral content. It is done by a trained technician and involves lying on a flat table above a source of x-rays while a very small dose of x-rays are passed through the body. We estimate this will take about 30 minutes. At all times, you will be able to talk with the technologist operating the machine and he/she with you. If you are a women who may become pregnant we will ask that you do a pregnancy test before a DXA study.
5) Biopsies: The biopsy involves taking a small sample of tissue from the lining of the colon, about the size of a grain of rice. The lining of the colon grows very quickly; within three days the place where the biopsy was taken can no longer be seen. A flexible sigmoidoscopy (flex sig) will be performed by a GI doctor. You do not have to do anything in advance to prepare (you don't have to drink anything). Sedation is not required. During the flex sig procedure 6 very small colon samples (the size of a grain of rice) will be taken from each of 2 areas of your colon (one at 25 centimeters and one at the splenic flexure). These samples will be sent to a lab for analysis. The risks and complications are rare but include bleeding and perforation. If the doctor sees a polyp they may remove it and send it to a lab for examination. The doctor will discuss this with you if this is done.
6) Regular weekly at home weights: a smart scale will be given to all participants to monitor their weight during the study. The smart scale is intended to avoid having you come into the clinic in order to check your weight. The weight data from this scale will be electronically sent to a server. An account will be created for you that does not reveal your identity (your real name and birthdate will not be used) in order to protect your privacy. Study staff will assist you to set up your scale and this account.
7) Regular weekly check in with study staff over email, phone, or video: During the first 6 months of this study a nutritionist/nutrition coach will support you as you select foods and manage your calorie intake to slowly lose weight. This activity should not take more than 30 minutes per week.
8) Stool collections: You will be given the things needed to collect a monthly stool sample to be returned to the study center for analysis.
9) 24-hr dietary recalls: We will ask you to participate in 2 unannounced phone/video calls to determine the foods eaten during the past 24 hours. These calls will take approximately 30 minutes each. In addition to the 2 calls completed during the screening week we will ask you to complete 2 more calls at approximately 12 weeks (3 months) into the study.
10) Pedometer: We will ask you to track your daily steps for 1 week using a study provided pedometer or your own device (e.g., smartphone with health app already on it). [You may use these devices for self-monitoring throughout the study if you wish to, it is optional.] A calendar is provided for data collection at study endpoints.

6 Months Study Visit

During the 25th week (~ 6 months) on the feeding study diet, we will ask you to return to the GCRC at Emory University to repeat the laboratory procedures that were completed just before (two 24-hour dietary recalls, weight, waist circumference) and at randomization: (questionnaires, fasting blood draw, urine collection, stool collection, DXA, biopsies, pedometers). If you wish, you will have the opportunity to provide feedback on the study experience and provide suggestions for improvement via a questionnaire. You will not receive food from the study after the 6 month study visit; however, the study nutritionist will continue to support you as you manage your weight. For the next 6 months we will ask you to continue the weekly at home weights, regular check in with the study nutritionist, and the monthly stool collections. Two 24-hour diet recalls will be collected at 6 months and will be repeated again at 9 months.

12 Months Study Visit
At approximately 52 weeks (12 months) of follow-up, we will ask you to return to the GCRC at Emory to repeat the laboratory procedures conducted at the 6 months study visit. The 12 month visit is the end of your active follow-up. If you wish, you will have the opportunity to provide feedback on the study experience and provide suggestions for improvement via a questionnaire.

Long-term Follow-up (until next colonoscopy)
Some study participants may have a follow-up screening colonoscopy at Emory during the funding period for this study or after this study ends. For those that do, we would like to ask them to notify of us of their colonoscopy date. We would also like to know the results of their colonoscopy (For example, "Did the doctor remove any new polyps?") We will also ask that participants repeat a subset of the laboratory procedures done at the previous GCRC study visits: two 24-hour dietary recalls, pedometers, weight, fasting blood draw, urine collection, stool collection and biopsies (collected during colonoscopy procedure). The tests could be done on the same day as the colonoscopy. We have included a separate consent line later in this document to confirm that participants are willing to be recontacted by the study after their one year of active participation.

Who owns my study information and samples?
If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used other than what is described in this form. If you withdraw from the study, data and samples that were already collected may be still be used for this study.

What are the possible risks and discomforts?
There may be side effects from the study procedures that are not known at this time.

Blood Draws
The most common risks and discomforts expected in this study are discomfort with the blood draws. There may be minor bruising at the draw site. Well-trained and experienced lab techs will take your blood. Blood sampling can also cause light-headedness or dizziness. If this occurs, having you lie flat with your feet raised will alleviate the symptoms. As with any procedure involving taking blood, infection is possible. The risk of this is very low. All precautions will be taken to avoid infection. There is a rare risk of developing a clot or swelling of the vein and surrounding tissue from the blood draw.

Flex Sig Biopsy
The flex sig procedure will be conducted by a gastroenterologist in a procedure room at the GCRC. There are minimal risks associated with this procedure. These include discomfort of the abdomen and in rare cases (less than 1%, approximately 1/1000) there may be bleeding or bowel perforation.

DXA
The Dual Energy X-ray Absorptiometry (DXA or DEXA) bone density procedure exposes an individual to a small amount of radiation where the X-ray beam crosses the body. If you are a female and able to become pregnant we will ask you to complete a pregnancy test before the DXA. Pregnant women should not have a DXA test and pregnant women are not allowed to continue in the study. The DXA radiation exposure is not necessary for your medical care and is for research purposes only. This protocol calls for a total body scan. You will be exposed to radiation from x-rays. These procedures are not necessary for your medical care and will occur

because you participate in this study. The estimated radiation dose that you will receive is equal to or less than the natural environmental radiation the average person receives in the United States annually. The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. The risk for radiation-induced cancer from this study is negligible.

Genetic Information

How is my Genetic Information Protected? What are the Risks?

The Genetic Information Nondiscrimination Act (GINA) is a federal law that 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 generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get 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 get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that GINA does **not** protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance, and does not apply to employers with less than 15 employees.

In addition to GINA, the State of Georgia has laws that prohibit insurers from using genetic testing information for any non-treatment purpose. However, like GINA, this state law protection has exclusions: life insurance policies, disability income policies, accidental death or dismemberment policies, Medicare supplement policies, long-term care insurance policies, credit insurance policies, specified disease policies, hospital indemnity policies, blanket accident and sickness policies, franchise policies issued on an insurance policy written as a part of workers' compensation equivalent coverage, or other similar limited accident and sickness policies.

Privilege

In the State of Georgia, in some circumstances your genetic information has may have special legal protections called "privilege." This means that the information cannot be used as evidence in a court. By allowing us to use and disclose your genetic information for this research study along with other information about you that genetic information used in the research may no longer have that legal protection. Other protections described in this form will still apply. There are also other confidentiality protections for research data in general under Georgia state law.

Other

The less common risks and discomforts expected in this study are: possible foodborne illness. The diets used in this study are healthy, and will meet your nutritional needs. Foods will be prepared according to accepted standards of sanitation and will be transported so that they remain cool before you can put them in a fridge. However, it is possible that incorrect food handling during shipping, storage or preparation, if not detected, could result in food-borne illness. Every effort will be made to safeguard against this possibility. Also, while the meals will provide some variety in the diets, there will be repeated meals, which you might tire of. The

daily menu will be repeated about every 14 days. This means that you'll likely be eating the same set of lunches and dinners every other week.

You may experience some level of embarrassment or discomfort from being asked to collect stool or urine samples. Instructions will be given to you to help reduce your concerns.

You may have some level of embarrassment or discomfort related to the questions about your dietary habits or your bowel function habits.

To ensure your privacy all research records will only be labeled with your study number.

Will I benefit directly from the study?

This study is not designed to benefit you directly, however, you may lose weight as a result of this study and you may view that as a benefit. This study is designed to learn more about how diet composition influences weight, colon cancer and associated biomarkers. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

You will not be paid for the study screening visit or for participating in the one-week diet run-in (other than receiving foods to take home with you for that week). You will get $250 for completing the study baseline data collection and randomization visit. You will receive $500 for completing the 6 month follow-up visit and $650 for completing the 12 month follow-up visit. Finally, you will receive $100 for participating in extended follow-up at the time of your next colonoscopy procedure. If you complete all study activities, including the extended follow-up visit, you will receive a total of $1500. Study payments will be processed after completion of each of the visits and will appear on your study volunteer debit card which you will receive after the screening visit.

In addition, if you complete all study activities you may keep the body weight scale provided by the study.

You may be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

What are my other options?

Since this is not a treatment study, the alternative is not to participate.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Release of Samples, Genomic Data and Health Information

Deidentified data from this study (data that has been stripped of all information that can identify you), including your de-identified genetic information, may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. This study will collect biospecimens, and the analysis of these samples might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen). While the databases will not have information such as your name, address, telephone number, or social security number, it may be possible to identify you based on the information in these databases and other public information (including information you tell people or post about yourself). The risk of this happening is currently very low. Although your genomic information is unique to you, you do share some genomic information with your children, parents, brothers, sisters, and other blood relatives. Consequently, it may be possible that genomic information from them could be used to help identify you. Similarly, it may be possible that genomic information from you could be used to help identify them. If your genomic information is linked back to you, someone might use this information to learn something about your health.

The samples and information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from. Your data and specimens from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information. In addition, it is possible that your biospecimens may be used for commercial profit; however, you will not share in this commercial profit.

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you (e.g., a polyp is discovered by the doctor conducting your flex sig test), we will inform you, although we expect that this will be a very rare occurrence.

Medical Record
The results of your study tests and procedures will be used only for research purposes and will *not* be placed in your medical record.

In Case of Injury
If you believe you have become ill or injured from this research, you should contact Dr. Hartman at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Neither Emory nor the sponsor will pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory and the sponsor have not, however, set aside any money to pay you if you are injured as a result of being in this study or to pay for this medical treatment. For Emory, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory employee. "Negligence" is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

Costs
There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research activities. If the study procedures result in any medical complications that would not fall under "injury" as discussed above, the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study
You have the right to leave a study at any time without penalty. If you wish to do so, you should provide the Principal Investigator (Dr. Hartman) or the Study Coordinator with a written and dated notice of that decision.

If you leave the study before the final planned study visit, depending on the timing of your departure, the researchers may ask you to have some of the final steps done, specifically:

- Sample collection, weight and waist circumference
- Results of any colonoscopy that you may undergo during the duration of the study

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

These are the expected reasons why the researchers may stop your participation:

- Diagnosis of a serious health issue (e.g., cancer)
- For women, pregnancy (weight loss is not appropriate for pregnant women)
- If it was believed to be in the participant's best interest for another reason.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the main study (one year of active follow-up) and for your participation in the extended follow-up to your next colonoscopy.

Main Study

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related procedures. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require abuse of elderly or disabled adults.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory may use and disclose your PHI to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The National Cancer Institute is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of

the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.

- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Other researchers and centers that are a part of this study.
    - Government agencies that regulate the research including: Office for Human Research Protections.
    - Public health agencies.
    - Research monitors and reviewers.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Optional Study: Long-term follow-up at next screening colonoscopy
We wish to follow-up with study participants in conjunction with their next scheduled screening colonoscopy. To do this, we request your permission to remain in contact with you beyond your one year of active study participation. At the time of your next screening colonoscopy we will ask whether you agree to provide blood (collected at the GCRC), urine, stool, (collected at home and returned to the GCRC) and biopsy samples (collected during the procedure). This is described under **Long-term Follow-up (until next colonoscopy)** on page 6.

Optional: Storage of Data and Samples for Future Research
We request your permission to save some of your specimens, blood, urine, and stool for future studies. The saved samples will be frozen and stored as long as they are usable for research.

> **Authorization for This Use of PHI is Required to Participate in Optional Study, but Not in Main Study**: You do not have to authorize the use and disclosure of your PHI for the optional study(ies). If you do not authorize the use and disclosure of your PHI for the optional study(ies), then you may not participate in the optional research study, but you can still be in the main research study.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact Dr. Terry Hartman at: Department of Epidemiology, [redacted]

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact Dr. Terry Hartman at [telephone number(s)]: [redacted] or after hours at [redacted]

- if you have any questions about this study or your part in it,
- if you feel you have had a serious reaction to something related to the study, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

Consent and HIPAA Authorization for Optional Study/Studies:

Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional study/studies previously described:

Long-term Follow-up (at next screening colonoscopy) _____Initials
Storage of Data and Samples for Future Research _____Initials

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TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study, and any optional studies you initialed above. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____

Name of Subject

_____ _____

Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

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Name of Person Conducting Informed Consent Discussion

_____ _____

Signature of Person Conducting Informed Consent Discussion **Date** **Time**