University of Illinois at Chicago
Research Information and Consent for Participation in Biomedical Research
"Gut Bacteria and Diet in Colon Cancer Risk in Humans – Longitudinal Study: Controlled Feeding Study"

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Sponsor: National Cancer Institute

About this research study
You are being asked to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

Taking part in this study is voluntary
Your participation in this research study is voluntary. You may choose to not take part in this study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with the University of Illinois Hospital and Health Sciences System (UI Health) and/or University of Illinois at Chicago (UIC).

This consent form will give you information about the research study to help you decide whether you want to participate. Please read this form and ask any questions you have before agreeing to be in the study.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

WHY IS THIS STUDY BEING DONE?	The purpose of this study is to test two different meal plans in patients with history of pre-cancerous polyps and determine if these meal plans alter certain groups of bacteria and their effects on the colon.
WHAT WILL HAPPEN TO ME DURING THE STUDY?	There are 11 total visits in this research study. During the study, you will visit UIC 8 times and Rush 4 times. On two occasions, you will visit both sites on the same day. Some surveys may be completed remotely prior to your research visits via emailed link and/or phone calls. The study procedures at UIC are as follows: **Before your 1st or 2nd diet: This visit takes place at both UIC and Rush.** • Agree to participate in research at UIC (complete this form) • Have calorie needs measured (before your 1st diet only) • Have body composition measured with a DEXA scan • Complete at 24 hour diet recall • Complete a food frequency questionnaire • Receive a stool collection kit and food log to take home to track your food intake **First food pick up for 1st or 2nd diet, stool drop off and non-fasting blood draw):**

	• Return stool sample and food log • Complete a blood draw (3 1/2 tablespoons) • Have your weight measured • Receive 1 week of food, a diet log, and instructions on tracking uneaten food (you might be asked to bring this food back) **2nd food pick up for 1st or 2nd diet**: • Return food log and uneaten food or photos • Have your weight measured • Receive 1 week of food, a diet log, and instructions on tracking uneaten food (you might be asked to bring this food back) **3rd food pick up for 1st or 2nd diet and non-fasting blood draw**: • Return food log and uneaten food or photos • Complete a blood draw (3 1/2 tablespoons) • Have your weight measured • Receive 1 week of food, a stool collection kit, a diet log, and instructions on tracking uneaten food (you might be asked to bring this food back)
HOW MUCH TIME WILL I SPEND ON THE STUDY?	This study is approximately 10 weeks in length. During this time, you will visit UIC 8 times. The information below accounts only for time spent at UIC **Study Visit 1 (Before your 1st diet): This visit takes place at both UIC and Rush.** This visit will take 2 hours at UIC **Food pick-ups:** Each of these visits will take approximately 30 minutes. **Before your 2nd diet: This visit takes place at both UIC and Rush.** This visit will take 1 hour at UIC
ARE THERE ANY	You will not benefit directly by participating in this research study.

BENEFITS TO TAKING PART IN THE STUDY?	Others may benefit in the future from the results of this study by helping us understand colorectal cancer risk.
WHAT ARE THE MAIN RISKS OF THE STUDY?	For this study, the main risks to know about are: ● Discomfort during blood draws ● Discomfort during stool sample collection ● Discomfort with diets ● Exposure to a small amount of radiation (as much as a trans-Atlantic flight during) DEXA scan ● Claustrophobia or discomfort while calorie needs are being measured ● Uncomfortable feelings during survey completion ● Discomfort during physical measurements ● Loss of confidentiality For details and a list of risks you should know about, please see the "What Are the Potential Risks and Discomforts of the Study" section below.
DO I HAVE OTHER OPTIONS BESIDES TAKING PART IN THE STUDY?	This is not a treatment study. Your alternative is not to participate in this study**.**
QUESTIONS ABOUT THE STUDY?	For questions, concerns, or complaints about the study, please contact Lisa Tussing-Humphreys, PhD, MS, RD at (312) 355-5521 or email at ltussing@uic.edu. If you have a research related injury, you should immediately contact Lisa Tussing-Humphreys, PhD, MS, RD at (312) 355-5521. If you have questions about your rights as a study subject; including questions, concerns, complaints, or if you feel you have not been treated according to the description in this form; or to offer input you may call the UIC Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu. If you have questions or concerns regarding your privacy rights under HIPAA, you should contact the University of Illinois HIPAA Privacy Office at (844) 341-2201 or hipaa@uillinois.edu..

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research. Please also feel free to ask the study team questions at any time.

Who may participate in the study?
You are being asked to participate in the research study because you have already agreed to participate in the study at Rush University Medical Center testing two different meal plans in patients with a history of pre-cancerous polyps and determine if these meal plans alter certain groups of bacteria or their effects on the colon. You were asked to take part because the study investigator at Rush (Dr. Mutlu) believed that you may be at an increased risk for colorectal cancer because you have had pre-cancerous type polyps during a previous colonoscopy. Pre-cancerous polyps are growths that form on the lining of your large intestine from which colon cancer typically arises.

We are now asking you to agree to participate in the portions of this study that are taking place at UIC. Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future dealings with the University of Illinois at Chicago.

Approximately 44 subjects may be involved in this study at UIC.

What procedures are involved?
This research will be performed at the Integrative Physiology Lab located in the UIC Disability, Health & Social Policy Building, at 1640 W. Roosevelt Rd, or at the Clinical Research Center at 914 S Wood. St. Suite 2. All food pickups will take place at the Applied Health Sciences Building located at 1919 W. Taylor Street, Chicago, IL, 60612 on the UIC campus.

If you agree to be in the study, you will be asked to do the following procedures:

Remote Surveys: If you are interested in advance of your first research visit, you will receive a link to a survey which should be completed 1-3 days before your research visit. You may also receive a phone call during which we will ask you about the foods that you have eaten in the last 24 hours, which is also called a 24 hour diet recall. We will also fill out a food frequency questionnaire that asks about your diet over the past year . This call will take between 75-90 minutes.

Before your 1st or 2nd diet: This visit takes place at both UIC and Rush. After agreeing to participate in the portion of the research taking place at UIC and reviewing and signing this form electronically, you will complete a test that measures how many calories your body needs (visit 1 only). We will use this information when we create your meal plan. You will rest for about 30 minutes and then wear a transparent hood that is connected to a metabolic monitor. You will need to lie still under the hood for about 30 minutes. The test may not be conducted due to health risks related to COVID-19. If the test is not conducted, we will use a mathematical equation to estimate your calorie needs. This will be followed by a Dual Energy X-ray absorptiometry (DXA) body composition scan which takes about 15 minutes. A DXA scanner is a machine that uses x-rays to measure body composition (percent of body fat, total body fat, and muscle mass and bone mass) that involves exposure to very low amounts of X-ray radiation. If you are female and pregnant, you cannot have your body composition tested using a DXA scan because it emits a small amount of radiation. Women that have had at least one menstrual period within the past six months will not qualify to participate in this study.

If surveys were not completed remotely, during this visit we will also ask you about the foods that you have eaten in the last 24 hours, which is also called a 24 hour diet recall. You will fill out a food frequency questionnaire that asks about your diet over the past year. You will also be handed a food log that we will ask you to fill out at home.

Electronic Visit: The day before your first food pick up, you will have the option to email us your completed diet log (scan or take photos and email to ahamm6@uic.edu). You can also choose to complete a survey about your GI symptoms through a link that will be emailed to you. The survey will take 5-10 minutes.

First food pick up for the 1st or 2nd diet, stool drop off and non-fasting blood draw: This will be the 1st food pick up visit for diet 1 or 2. You will give the study coordinator your stool sample (and the date of stool collection) and you will be asked about the method of storing the sample. You will also be asked to turn in your food log and we will review the log with you. You will be asked about medication use. If you have not provided a stool sample at this visit, we will not able to give you the study food or start you on the diet and we will schedule a new pick up date. If you have started antibiotics, we will also not be able to give you the study food or start you on the diet and you will no longer qualify for the study. All meals will be provided in prepackaged form with breakfast, lunch, dinner, beverages, snacks and condiments. Seven days of meals will be provided at a time. You will be instructed to keep a daily food log and will be asked to return this log at each food pick-up. For each week, you will be asked to photograph or save any uneaten foods and beverages in the original packaging and bring with you to the next food pick one week later. A non-fasting blood sample (50 mL or 3 ½ tablespoons) and your body weight will also be collected at this visit to measure bile acids and other factors in your blood related to bacteria in your intestines. The blood and stool sample will be delivered to Rush where it will be processed and stored by Dr. Mutlu's lab. This visit will take approximately 30 minutes.

Electronic Visit: The day before your second food pick up, you will have the option to email us your completed diet record as well as any photographs taken of uneaten foods (scan or take photos and email to ahamm6@uic.edu). You can also choose to complete a survey about your GI symptoms through a link that will be emailed to you. The survey will take 5-10 minutes.

2nd food pick up for 1st or 2nd diet: This visit takes place at UIC one week after the first food pick-up. At this visit, research staff will collect from you any uneaten foods/review photos, measure your body weight, and review with your daily food logs. You will give the study coordinator your stool sample (and the date of stool collection) and you will be asked about the method of storing the sample. The stool sample will be delivered to Rush where it will be processed and stored by Dr. Mutlu's lab. Seven days of meals will be provided. You will receive new daily food logs and we will review with you how to keep a daily food log; you will be asked to return this log at the next food pick up. You may be asked to continue to collect your uneaten foods and beverages. This visit will take approximately 20 minutes.

Electronic Visit: The day before your second food pick up, you will have the option to email us your completed diet record as well as any photographs taken of uneaten foods (scan or take photos and email to ahamm6@uic.edu). You can also choose to complete a survey about your GI symptoms through a link that will be emailed to you. The survey will take 5-10 minutes.

3rd food pick up for 1st or 2nd diet and non-fasting blood draw: This visit takes place at UIC one week after your last food pick-up. At this visit, staff will collect any uneaten food from you (if we ask you to retain your uneaten foods) or review photos of uneaten foods, measure your body weight, and review your daily food logs. You will give the study coordinator your stool sample (and the date of stool collection) and you will be asked about the method of storing the sample. We will collect a non-fasting blood sample (50 mL or 3 ½ tablespoons). The blood and stool samples will be delivered to Rush where it will be processed and stored by Dr. Mutlu's lab. Seven days of meals will be provided. You will receive new daily food logs and we will review with you how to keep a daily food log; you will be asked to return this log at visit 5/10 at Rush. You may be asked to continue to collect your uneaten foods and beverages. The study coordinator will provide you with a new stool collection kit to collect a sample before your next visit.. You will be asked to collect a stool sample and bring it to your next visit which will be visit 5/10 at Rush University Medical Center. This visit will take approximately 30 minutes.

Dietary compliance assessments in addition to the above visits:
In order to ensure that you are indeed following the provided diets you will be asked to comply with the following:

1) You may receive an unannounced phone call and be asked to provide a 24-hour dietary recall. This will take no longer than 30 minutes.
2) Your weight will be taken each week when you go to pick up your meals from UIC. The provided diets are specifically formulated for your weight to remain stable thus your weight is expected to remain the same.
3) You will be asked to keep daily records of consumption of food provided when you are consuming the experimental diets and you will also be asked to keep diaries of any additional foods you consume that were not provided to you.
4) The study team may provide additional counseling so that you can follow the diet that you are given, if needed.

Prohibited medications. In order to ensure that the medications you may be taking do not interfere with the dietary effects of the study, you will be asked to not start taking Carbose (a medication that lowers blood sugar in pre-diabetic patients), Cholestyramine (medication taken for high cholesterol levels), Probiotics (potentially beneficial bacteria found in pill form), Prebiotics (dietary supplements that make beneficial bacteria grow in your intestines), aspirin doses which are above 81mg per day or 325 mg every other day for prevention of cardiovascular disease, blood thinning medications, vitamin pills or herbal supplements over the counter, and antibiotics if possible. If you need to start an antibiotic, you will not be able to continue in the rest of the study and we ask that you notify the study coordinator.

During this study, Dr. Lisa Tussing-Humphreys and her research team will collect information about you for the purposes of this research. This information will include past medical history, family medical history, demographic information (race, gender and date of birth), colonoscopy results from your medical record, medication and dietary supplement use, your lifestyle behaviors including diet, smoking and alcohol use, your weight, height, and body fat amount and distribution, and diet compliance information. This information will help us understand how diet, and bacteria in the stool and intestinal lining relate to colon cancer risk and adenoma type polyps

What will happen with my information and/or biospecimens used in this study?
Biospecimens are samples of material, such as urine, blood, tissue, cells, etc. Biospecimens are stored in a repository or bank and are used for laboratory research.

Your identifiable private information and/or identifiable biospecimens collected for this research study may be used for future research studies and/or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information and/or biospecimens are shared. Once the identifying information is removed, the information and samples cannot be withdrawn from further use. You will not be asked for additional consent.

In future, we may use the specimens collected as a part of this study for whole genome sequencing, which involves mapping all of your DNA. This would help researchers to understand how a person's DNA might affect the type of bacteria on the colon and in the stool, and how these bacteria behave that increases/decreases a person's risk for colon cancer and adenoma type polyps. This information would be stored with your unique study ID on a secure password protected server. If we map your DNA, you would not receive this information.

Will I receive my results from the study?
We will not share results of the study with you.

What are the potential risks and discomforts of the study?
Side effects, risks, and/or discomforts from participation in this study include:

→ 1. ***Blood draws.*** We will draw your blood on 4 occasions at UIC. There are minimal risks associated with blood draws. Drawing blood involves placing a tight wrap on your upper arm, inserting a needle into a vein in your arm and withdrawing blood. You may experience discomfort at the time of blood draw and/or bleeding, and bruising at the site where the needle enters the body. In rare cases, fainting or infection may occur. Care will be taken to reduce these risks by having a trained clinician or research staff member conduct the blood draw.

→ 2. ***Stool sample collection.*** You will be asked to collect a stool sample 6 times throughout the study. We will receive your stool sample at UIC on 6 occasions. Collecting a stool sample involves placing a "hat" that will be provided by our staff on your commode (toilet) before you are seated. This hat will collect the stool and then you can use a wooden stick and protective gloves, which will be provided by our staff, to transfer the stool sample into special zip lock bags. The special zip lock bags that contain the stool samples require refrigeration until you bring it into the study office. Both of the special zip lock bags will have a fluid inside and you will be asked to press on the outside of the zip lock bag with your fingers to make sure the fluid is mixed with the stool sample you have provided. You may experience emotional stress related to working with your own stool. Mishandling stool can lead to infections. However, stool collection instructions will be reviewed with you and a safe hand washing technique will be taught to reduce risk of

infection.

→ 3. ***Diets.*** An additional potential risk is imposed by the diets. The two diets are designed so that you maintain your weight within 2% of your body weight before starting a diet (measured at Rush). All foods, beverages, and condiments will be provided. Water, non-caloric and caloric non-cola soda will be provided consistently across the two diets. The relatively short 3 week exposures to safely-prepared diets is not expected to pose risk. The UIC diet team has food sanitation training and certification. We ask that you communicate immediately with Dr. Tussing-Humphreys (312-355-5521) any changes to your health that you think might be related to consuming the diets.

→ 4. ***Body composition scan with DXA.*** The DXA scan is done in this study to measure your body composition and it uses X-rays that yield precise, high quality images of your body compartments (e.g., fat and muscle tissues). It involves exposure to very low amounts of X-ray radiation. Every person is exposed daily to natural background radiation from sources like soil, rocks, radon, and natural radiation in our bodies, the sun, and outer space. A DXA total body scan delivers an amount of radiation similar to what you may be exposed to on a trans-Atlantic flight (0.77 μC/kg body weight) and imposes no major risk to non-pregnant women or men. All persons have a risk up to several percent, depending on age, of developing a cancer (or second cancer) over their lifetime, even if they receive no medical radiation at all. Medical radiation can increase that risk, however, depending on its dose and where in your body it is directed. In most cases, your cancer risk after receiving medical radiation is so slightly increased from your natural cancer risk that the difference is hard to measure. To reduce risks associated with a DXA, pregnant women and women who have menstruated in the past six months will not be included in this study.

→ 5. ***Indirect calorimetry testing***. You may feel a little claustrophobic during the indirect calorimetry testing because a clear hood is placed over your head so that we can measure the air you are breathing out. To make your feel more comfortable, the test will be conducted in a private room while your lay on a comfortable cot with pillow. We will dim the lights so that you can remain relaxed. The test will be formed by a trained and experienced researcher.

→ 6. ***Surveys***. Responding to study questionnaires is not expected to but, may provoke uncomfortable feelings or cause mild distress. Participants who experience any of these symptoms may choose not to answer any question that cause them discomfort, or may choose to withdraw from the study altogether.

→ 7. ***Physical measurements***. We will check your weight at the food pick up visits, which may cause discomfort. Trained research staff will measure your weight in a private area.

→ 8. ***Loss of confidentiality.*** Because you are sharing personal information, there is always the possibility that confidentiality will be violated. However, every precaution will be taken to keep your information safe. You will be given a study ID number to protect your identity. Data will be stored in locked filing cabinet (this form) in Dr. Tussing-Humphreys office located at 1919 W Taylor St. Your subject ID and date of birth will be stored on the machine used to measure your calorie needs, the DXA machine and the laptop used to collect your diet data. This equipment is kept in secure locked areas. Survey data will be stored in an electronically in a password protected, restricted access electronic database at ***Rush University Medical Center***. Only authorized research personnel will have access to this information. Your blood and stool will be transferred, processed and stored with you study ID only at ***Dr. Ece Mutlu's lab at Rush University Medical Center located at 1725 W. Harrison St., Suite 207, Chicago IL, 60612.*** Your blood and stool samples will be sent to Dr. Rex Gaskins and Dr. Jason Ridlon's labs at the University of Illinois at Urbana Champaign for analysis. Only your study ID, sample type, and date we collected the sample will be labeled on these samples.

There may be risks from the study that are not known at this time.

Although we are not conducting genetic testing in this study, if you agree to allow us to store your remaining samples for future research there is the possibility that we would use these samples for genetic analysis. While we believe that the risks to you and your family are very low, we are not able to know all of the risks from taking part in genetic research studies. Your privacy will be protected to the fullest extent possible. Certain health concerns that affect you and your blood relatives might be found as inherited traits are studied. Even though your genes are unique, you share some of the same genes with your blood relatives. In addition, there may be undue stress, anxiety, or embarrassment resulting from inadvertent disclosure of information on family relationships, ethnic heritage, or potentially stigmatizing conditions.

There is a Federal law called the Genetic Information Nondiscrimination Act (GINA). In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. For example, life insurance companies may charge a higher rate based on this information. GINA also does not protect you against discrimination if you have already been diagnosed with the genetic disease that is being tested in this research study.

What about privacy and confidentiality?

Efforts will be made to keep your personal information confidential; however, we cannot guarantee absolute confidentiality. In general, information about you, or provided by you, during the research study, will not be disclosed to others without your written permission. However, laws and university rules might require us to tell certain people about you. For example, study information which identifies you and the consent form signed by you may be looked at and/or copied for quality assurance and data analysis include:

- Representatives of the university committee and office that reviews and approves research studies, the Institutional Review Board (IRB) and Office for the Protection of Research Subjects.
- Other representatives of the State and University responsible for ethical, regulatory, or financial oversight of research.
- Government Regulatory Agencies, such as the Office for Human Research Protections (OHRP).
- The National Institutes of Health.
- The National Cancer Institute.

A possible risk of the study is that your participation in the study or information about you and your health might become known to individuals outside the study. Your personal information, research data and specimens will be de-identified, kept in locked cabinets, and encrypted to prevent access by unauthorized personnel Your study information will be given to the National Institutes of Health and National Cancer Institute with your information in a de-identified format.

Your individual data will be held in the strictest confidence until 6 years after the study is terminated, at which point all research materials, including blood and stool samples, will be destroyed or properly discarded.

When the results of the study are published or discussed in conferences, no one will know that you were in the study

A description of this study 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.

Will health information about me be created, used or shared with others during this study?

State and federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect your health information. This section of the form describes how researchers, with your authorization (permission), may use and release (disclose or share) your protected health information in this research study. By signing this form you are authorizing Dr. Lisa Tussing-Humphreys and her research team to create, get, use, store, and share protected health information that identifies you for the purposes of this research. The health information includes all information created and/or collected during the research as described within this consent form and that specifically includes the results of the blood, tissue, stool, saliva, hair, and urine samples, DXA scan (body fat and muscle mass), ultrasound (abdominal fat), height/weight, questionnaires, and dietary recall interviews that are part of the research that will become PHI, including personal identifiers such as name, address, telephone number, demographic information, e.g. age, race, gender and date of birth.

During the conduct of the research, the researchers may use or share your health information:
- With each other and with other researchers involved with the study;
- With law enforcement or other agencies, when required by law;

- With the sponsor/funding agency of the research, National Institutes of Health, as required to conduct the research and if the research results need to be confirmed;
- With representatives of government agencies (i.e., Food and Drug Administration), review boards including the University of Illinois at Chicago Institutional Review Board, the University of Illinois Medical Center and its representatives, and other persons who watch over the safety, effectiveness, and conduct of research.

If all information that identifies you is removed from your health information, the remaining information is no longer participant to the limits of this Authorization or to the HIPAA privacy laws. Therefore, the de-identified information may be used and released by the researchers (as permitted by law) for other purposes, such as other research projects.

How will your health information be protected?

The researchers and the National Institutes of Health agree to protect your health information and will only share this information as described within this research consent/authorization form.

When your health information is given to people outside of the research study, those agencies that receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it. They may also share your information with others without your permission, if permitted by laws that they have to follow.

What if I am injured as a result of my participation?

If you get ill or injured from being in the study, UIC will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Lisa Tussing-Humphreys, PhD, MS, RD at (312) 355-5521.

You should let any health care provider who treats you know that you are in a research study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact the research doctors.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial. UIC has not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to you for research related illnesses or injuries. The only exception to this policy is if it is proven that your injury or illness is directly caused by the negligence of UIC.

→ By signing this form, you are not giving up any legal rights to seek compensation of injury.

What are the costs for participating in this research study?
There are no costs to you for participating in this research study.

Will I be reimbursed for any of my expenses or paid for my participation in this research study?
You will receive $50 after completion of your baseline visit, $100 after completion of the first diet, $150 after completion of your second baseline (before the second diet) and $500 at completion of the second diet. If you complete all portions of the research study, you will have received a total of $800. All payments will be made via check mailed to your home. We will also provide validation for UIC parking if you wish to drive or $7 for reimbursement by for public transportation at each research visit.

Your participation in this research study may contribute to the development of commercial products from which the others may derive economic benefit. You will have no rights to any products, patents or discoveries arising from this research, and you will receive no such commercial economic benefit.

Your participation in this research study may contribute to the development of commercial products from which the Sponsor company or others may derive economic benefit. There are no plans to compensate you for any of these developments.

Will I be told about new information that may affect my decision to participate?
During the course of the study, you will be informed of any significant new research findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study may be re-obtained.

Can I withdraw or be removed from the study?
If you decide to participate, you have the right to withdraw your consent and leave the study at any time without penalty.
The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests.
- You were to object to any future changes that may be made in the study plan.

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Lisa Tussing-Humphreys in writing at the address on the first page. Dr. Lisa Tussing-Humphreys may still use your information that was collected prior to your written notice.

What if I am a UIC employee?
Your participation in this research is in no way a part of your university duties, and your refusal to participate will not in any way affect your employment with the university, or the benefits, privileges, or opportunities associated with your employment at UIC. You will not be offered or receive any special consideration if you participate in this research.

Remember:
Your participation in this research study is voluntary. Your decision whether or not to participate will not affect your current or future relations with the University. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Signature of Subject or Legally Authorized Representative
I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to participate in this research study. I will be given a copy of the signed and dated form.

_____ _____
Signature Date

_____
Printed Name

_____ _____
Signature of Person Obtaining Consent Date (must be same as subject's)

_____
Printed Name of Person Obtaining Consent