Protocol Title: Randomized Controlled Trial Examining the Effects of Meal Timing among Obese Individuals

NCT Number: NCT03354169

Principal Investigators: Dr. Kelly Allison and Dr. Namni Goel

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UNIVERSITY OF PENNSYLVANIA RESEARCH SUBJECT COMBINED INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title: Randomized Controlled Trial Examining the Effects of Meal Timing among Obese Individuals

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Emergency Contact: For a psychiatric or medical emergency, please go to your nearest emergency room.

Why am I being asked to volunteer?

You are being invited to participate in a research study because you live or work within a 5 mile radius of the Hospital of the University of Pennsylvania and you are willing to follow study instructions on the timing of your meals and snacks throughout the day.

Your participation in the study will help us to determine the effect that timing of eating may have on weight and metabolism. Your participation is voluntary, which means you can choose whether or not you want to participate. Your choice to participate or not to participate will not result in any loss of benefits to which you are otherwise entitled.

Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The study involves an interview and questionnaires, record-keeping of your eating and sleeping patterns, testing of your metabolism, a scan to assess your body fat, a fat tissue biopsy, and a series of blood draws,

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all of which this form will describe in more detail. Our research team will talk to you about the research study, and we will give you this consent form to read. You may also decide to discuss it with your family, friends, or treatment team. You may find some of the medical language difficult to understand, so if you have any questions, let us know. If you decide to participate, you will be asked to sign this form. Your doctor may be an investigator in this research study. As an investigator, your doctor is interested both in your clinical wellbeing and in the conduct of this study. Before entering this study or at any time during the research, you may want to ask for a second opinion about your care from another doctor who is not an investigator in this study. You do not have to participate in any research study offered by your doctor.

What is the purpose of this research study?

The purpose of this study is to test the effect of two different eating schedules (daytime or delayed) on your body weight and fat content, metabolism, certain markers of metabolism in your blood, and expression of genes in your blood and adipose (fat) tissue. The daytime schedule includes eating all foods between 8am and 7pm and the delayed schedule includes eating all foods between 12pm and 11pm.

How long will I be in the study?

Your participation in the study will take place over a period of approximately 19 weeks (about 4.5 months). There will be 40 participants in this study, with the overall study lasting five years.

What am I being asked to do?

The study consists of the following phases – screening, assessment visit 1, eating condition 1, assessment visit 2, a wash-out period, assessment visit 3, eating condition 2 and assessment visit 4, as discussed in detail below. The assessment visits will all consist of the same procedures and will take place at the Center for Human Phenomic Science (CHPS) of the Hospital of the University of Pennsylvania before and after each of the eating conditions, four times total. The four 31-hour inpatient assessments will consist of blood draws, adipose (fat) tissue sampling, a dual energy X-ray absorptiometry (DEXA) scan, and a resting metabolic rate test. These procedures are described in more detail below in the assessment visit day 1 procedures and the assessment visit day 2 procedures.

<u>Screening</u>
In order to determine whether you are eligible to participate in this study you must undergo the following:

1) A complete physical examination

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2) Tests of your blood to determine if you have any conditions such as diabetes or any serious, uncontrolled medical condition that may interfere with your participation in the study.
3) An Electrocardiogram (EKG) test to determine if you may have any cardiac issues that may interfere with your participation in the study.
4) Urine Pregnancy Test. A pregnancy test will be given to women at this screening visit, with the exception of post-menopausal women and women who have had surgeries or treatments, such as a hysterectomy, that make them infertile.
5) Urine Drug Screening

If you are pregnant, are nursing, have a sleep disorder, do night-shift work, take certain medications or work for any of the investigators participating in this study, you will not be able to participate in the study.

During the screening period, you will also be asked to:

1) Complete several self-report questionnaires and a structured interview with the study staff to assess your mood and exercise, sleeping and eating patterns to see if you meet the study requirements.
2) Keep a log, during the 10 days of the screening assessment, where you will record all food and beverages that you eat and drink along with when you sleep and when you exercise. Your activity will be measured by a small electronic wrist activity recorder, called an Actigraph (about the size of a wrist watch), during this time. This recorder, similar to a pedometer, records all activity in your arm, and is very useful in determining if and when you get up at night.

Please note that you will return the activity recorder and log to Dr. Allison, Dr. Goel or study staff for analysis at the end of the 10 days. You are expected to return all study materials, including the Actigraph, log, and self-report questionnaires.

<u>Assessment Visit 1</u>
Following successful completion of the screening period, you will complete assessment visit 1. All assessment visits will follow the same protocol as indicated below, with two exceptions – 1) randomization will occur after you have completed assessment visit 1 to determine which eating condition you will begin first and 2) at the end of assessment visit 4 you will be asked to complete a 10-minute survey regarding your reflections on the study overall.

Assessment Visit Day 1 Procedures
The visit will include 31 hours (overnight) spent at the CHPS, where your meals and snacks will be provided. At each of the assessment visits you will be given a urine drug screening and, if appropriate, a pregnancy test. While you are in the hospital room, the lights will be dim, so you will not be able to bring anything into the room that will emit any extra light, such as a laptop, smartphone, tablet, etc. You will be able to bring books, paperwork, or other things to occupy your time.

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There is a television in the room with a standard channel lineup that you will be able to watch. There is also a telephone and free local calling provided to you during your stay.

Prior to your arrival, you will be asked to fast overnight (no food, only water) after 11:00 pm the night before your assessment visit. You will also be asked to refrain from using toothpaste, mouthwash, or chewing gum after 11:00 pm the night before your assessment visit, as well as during the morning of your visit. You will arrive at the CHPS at the Hospital of the University of Pennsylvania at 7:00 am. Starting at 8:00 am, your blood will be drawn every four hours. A thin needle (an introducer) will be inserted into a vein in your forearm, much like an IV line. Very small blood samples, 12.5mL (about 2.5 teaspoonfuls), will be collected every four hours from 8:00 am on Day 1 through 8:00 am on Day 2; so you will sleep through the night with the intravenous IV line. From this blood we will examine gene expression and hormones related to metabolism, eating, and sleep. An additional 10ml (2 teaspoons) of blood will be collected during the first assessment visit and will be saved and stored as whole blood. This sample will later be analyzed for the entire genome to provide us with more complete information as to how all genes may contribute to metabolism, sleep and circadian (24-hour) rhythms, an important area of interest to our research. In addition to blood draws, every 4 hours you will be providing a sample of saliva using a salivary swab to examine changes to the human salivary microbiome. In order to provide this sample, you will be asked to place an absorbent cotton swab into your mouth and slowly move the swab around in your mouth for 5 minutes. After the 5 minutes is up, you will be asked to place the swab into a small plastic tube where it will be stored.

Following the first blood draw, we will measure your resting metabolic rate for 45 minutes. During the measurements, you will lay on your back in bed with a plastic hood/canopy over your head and neck. You will lay still and breathe normally while the air you inhale and exhale is collected in the canopy/hood and analyzed using a machine that is connected to the canopy/hood. Following the metabolic measurement your body composition will be measured using a DEXA scan. During this test, X-ray pictures of your body will measure how much fat and muscle are present. You will lie flat on a table and a machine will take pictures of different areas of the body. This will take about 20 minutes.

Following the 12:00 pm blood draw, a sample of your fat tissue will be taken. During this procedure, you will have a fat tissue biopsy (small tissue sample, about the size of a grape) taken from under the skin in your buttocks, performed under local (on the area where the biopsy will occur) anesthesia (numbing medication – 2% Lidocaine) through a small (4mm) incision, about the size of a staple. The incision will be closed using steristrips, which are small pieces of sterile (germ free) tape placed on the skin. These strips will fall off in about 4 days and do not need to be removed by a doctor. The purpose of getting blood and fat cells is to help investigators understand how expression of certain genes change in different parts of the body with the two different eating conditions. After the completion of the fat tissue biopsy, you will be asked to complete a seriesof

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computer-based cognitive tasks, administered by the research staff. These computer tasks will take approximately 25-30 minutes.

You will be provided meals and snacks during your visit, and you are free to watch television or participate in other sedentary pastimes while you are there. You will be given several self-report questionnaires to complete during your stay to assess various psychological areas of interest. The last snack will be offered around 9:00 pm, after which you will fast overnight in preparation for the Frequently Sampled Intravenous Glucose Tolerance (FSIGT) test the following morning.

Assessment Visit Day 2 Procedures
After an overnight fast, you will undergo the Frequently Sampled Intravenous Glucose Tolerance Test (FSIGT) at 8:00 am. For the FSIGT test, we will insert one additional catheter/intravenous IV line (needles with tubes attached to them) for a total of two. Therefore, you will have one in a vein in one arm and one in a vein in the other arm. IVs make it possible to take frequent samples of your blood without having to puncture skin each time. One of the IVs will be used for collecting blood, the other for the infusion of glucose (a sugar) and insulin (a hormone). Both glucose and insulin are found naturally in your body. The arm that is being used for sampling blood may be put into a heating pad. Heating the arm makes it easier for us to take samples of your blood. Thirty minutes after the morning IV is inserted we will begin blood sampling. After drawing a small amount of blood, glucose will first be infused into one of the IV lines. Twenty minutes later, we will inject insulin into that same IV. Multiple blood samples will be drawn over 3 hours to check how your glucose and insulin levels respond to the injections. The test will take approximately 4 hours to complete. The total number of blood samples taken during this procedure will be 24, each of 4mL, for a total of 96 mL or about 6.5 tablespoons (or 19.5 teaspoons, less than ½cup).

Following the FSIGT test, you will be served breakfast. After breakfast during the first assessment visit, you will be randomly assigned to start with one of two eating conditions for the next 8 weeks: 1) Daytime or 2) Delayed. Following randomization, you will be discharged from CHPS.

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Procedures	Initial Contact	Screening	Determine Eligibility	Assessment Visit 1 (at CHPS)	Eating Condition 1 (8wks)	Assessment Visit 2 (at CHPS)	Washout Period (2wks)	Assessment Visit 3 (at CHPS)	Eating Condition 2 (8wks)	Assessment Visit 4 (at CHPS)
Telephone Screen and Schedule Appt.	x									
Structured Interview and Screening Questionnaires		x								
History and Physical		x								
Wear Actigraph		x		x	x	x	x	x	x	x
Maintain Food, Sleep-wake, and Activity Logs		x		x	x	x	x	x	x	x
Study Staff Receive Logs and Actigraphy Data			x							
Blood Draws (every 4h for 24h)				x		x		x		x
Saliva Samples (every 4h for 24h)				x		x		x		x
Self-Report Questionnairres				x		x		x		x
Anthropometry and Blood Pressure		x		x		x		x		x
EKG		x								
Metabolic Testing (REE and RQ)				x		x		x		x
DEXA				x		x		x		x
Adipose Tissue Biopsy				x		x		x		x
Cognitive Inhibition Test Battery				x		x		x		x
FSIGT				x		x		x		x
Follow Prescribed Eating Times (All Food Provided)				x	x	x		x	x	x
Complete Daily Queries for Sleep, Exercise, and Eating Schedule					x				x	
Follow Preferred Eating Times (Own Food)			x				x			

Eating Condition 1

If you are assigned to the Daytime eating condition first, you will be asked to consume all of your meals and snacks each day between 8:00 am and 7:00 pm. If you are assigned to the Delayed eating condition first, you will be asked to consume all of your meals and snacks between 12 noon and 11:00 pm each day. You will eat on this schedule for 8 weeks. During the 8-week eating condition periods, all of your meals and snacks will be provided by the research kitchen,

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which you can pick up in person, or have delivered to you by a member of the research staff about every 3 days (twice per week). You will be provided a personalized menu and asked to track each food item you consume and the time you eat it. You will also be asked to record any beverages you consume on this menu (beverages will not be provided). If occasionally you do not eat the meals provided, you will be asked to use your smartphone or electronic device to send a picture of your food to the study team before you eat it, and again if any food is not eaten when you have finished your meal. You will be asked to wear an Actigraph for the duration of the study, and study staff will deliver new devices and collect used devices. You will be sent and asked to respond to daily queries by text message or email regarding your eating, sleeping, and exercise. You will be asked to attend a mid-condition check in with the study team at the beginning of week 4. During this check in you will have a blind weigh in, return your Actigraph and receive a new one, and you will be given several questionnaires to complete during the upcoming week. You will return those questionnaires with your food pick-up/delivery the following week.

Assessment Visit 2
At the end of 8 weeks of eating condition 1, you will complete assessment visit 2, following the same procedures as described previously. Following completion of assessment visit 2, you will complete the two-week washout period.

Washout Period
During this two-week period, you will be asked to eat as you normally would and eat what and when you like. No food is provided during this period.

Assessment Visit 3
After completion of the two-week washout period, you will then complete assessment visit 3, following the same procedures as described previously.

Eating Condition 2
Following assessment visit 3, you will start the second eating condition (Delayed for those initially assigned to the Daytime schedule; Daytime for those initially assigned to the Delayed schedule). You will be asked to eat on this new schedule for 8 weeks. You will be asked to attend a mid-condition check in with the study team at the beginning of week 4, which involves the same procedures as eating Condition 1.

Assessment Visit 4
At the end of the 8 weeks of eating condition 2, you will then complete the fourth and final assessment visit, following the same procedures as described previously. At the conclusion of assessment visit 4, you will be asked to complete a 10-minute survey regarding your reflections on the study overall.

After this final assessment visit, your participation in the study will be complete.

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What are the possible risks or discomforts?

- During this study you will be asked questions of a personal nature, such as your weight, age, eating and physical activity habits, and mood. You may experience some discomfort when answering these questions.

- You may not like all of the foods that we give you which may cause some discomfort. Additionally, the eating schedule may be difficult to manage at times, and this may cause you some inconvenience.

- You will experience the inconvenience of wearing the wrist activity recorder and keeping records of your eating behaviors, sleep, and activity throughout the study.

- For the blood draws, you will experience discomfort on initial insertion of the thin needles (introducer) into a vein on your arm and hand. Bruising may develop at the sites of the needle insertions. Dizziness or fainting is a remote possibility. Local clots may form, and infections may occur, but these are rare. The amount of blood drawn will not significantly reduce your blood volume, although there may be a small decrease in your red blood cell concentration (hematocrit). The total volume of blood drawn will be less than 50 teaspoonfuls per assessment visit, and this loss is readily restored.

- Occasionally, mild discomfort may occur from a catheter in your vein. If this happens, we will either change its position or remove it entirely, asking your permission before reinserting it. There may be some bruising when the catheters are removed. You will be asked to apply pressure to the site of each catheter for 10 minutes after its removal. There may be a small scar at the catheter sites that will disappear over the course of several months.

- This research involves exposure to radiation from the DEXA scans. Therefore you will receive a radiation dose. This radiation dose is not necessary for your medical care and will occur only as a result of your participation in the study. At doses much higher than you will receive, radiation is known to increase the risk of developing cancer after many years. At the doses you will receive, it is very unlikely that you will see any effects from the radiation dose.

- Risks associated with the fat biopsy include bleeding, bruising, infection, possible scarring, and pain. These risks will be reduced by using a trained physician/nurse practitioner to perform the procedures, local anesthesia to reduce pain, and careful monitoring of the site where the fat cells were taken.

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- For the FSIGT test, a known risk is low blood sugar. We will administer insulin 20 minutes after the glucose is given to you to ensure that your blood sugar returns to normal. As insulin lowers blood glucose, there is a possibility that the insulin will make your blood glucose go too low. Low blood sugar results in sweating, shaking, and mental confusion. We will monitor your blood sugar and give you food or glucose directly into your blood if your blood sugar goes too low.

- The study involves restraining you from eating for a period of at least 10 hours (overnight) while in the hospital, which may be uncomfortable.

- During the assessment visits you will be staying in a dimly lit room and will be unable to bring any electronics that will emit any extra light, such as your cell phone. This may be an inconvenience.

- If you are currently pregnant or become pregnant while in the research study, it is important that you inform the investigator because you will not be able to participate. If you are able to become pregnant, you must be given a pregnancy test during the screening period and at each assessment visit. You are asked to use a medically accepted method of birth control (such as condoms, birth control pills or patches, IUDs, etc) while you participate in the study.

- The research may involve risks that are currently unforeseeable.

- If you are injured, you should inform the treating physician that you are in a research study.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

You are not expected to get any benefit from being in this research study. Your participation may contribute important data for understanding how eating at certain times of day affects weight management and how the body processes and stores food.

What other choices do I have if I do not participate?

The only alternative is not to participate.

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Will I be paid for being in this study?

You will receive $500 for each of the 4 CHPS assessments you complete, with a $300 bonus at study completion ($2300 total).

Please note: In order to be compensated for your participation in this study, you must provide your Social Security Number. Additionally, please note that the University of Pennsylvania is required to report to the IRS any cumulative payments for participation in research studies that exceed a total of $600 in a calendar year.

Will I have to pay for anything?

All interviews and tests that are part of this protocol will be provided at no cost to you.

What happens if I am injured from being in the study?

If you have a medical emergency during the study you should go to the nearest emergency room. You may also contact the Principal Investigator, Kelly Allison, Ph.D. (215-898-2823)), as well as your own doctor, or seek treatment outside of the University of Pennsylvania. Be sure to tell the doctor or his/her staff that you are in a research study being conducted at the University of Pennsylvania. Ask them to call the telephone numbers on the first page of this consent form for further instructions or information about your care. In the event that you are hurt or injured as a result of participation in this research study, please contact the investigator listed on page one of this form.
We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them. There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researchers' names and phone numbers are listed on the consent form.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end in 5 years, after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time by your physician or the study Sponsor without your consent because:

- The Primary Investigators feel it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.

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- The study Principal Investigators have decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Withdrawal will not interfere with your future care.

Who can see or use my information? How will my personal information be protected?

Personal information is anything that can be used to identify who you are. Examples include name, address, telephone number, medical record number, social security number or e-mail address. We will do our best to make sure that the personal information obtained during the course of this research study will be kept private. However, we cannot guarantee total privacy. You will be assigned a subject identification number. This consists of your initials and a random number that is not coded or affiliated with your identity. The subject identification number will be used on most study documents in place of your name. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Study records, including those containing personal information, will be kept in a locked office, in password protected and institutionally secured and managed computers, and in password protected and institutionally secured and managed network storage in efforts to protect your privacy. The IRB at the University of Pennsylvania will have access to the records. Your personal health information and results of tests and procedures are being collected as part of this research study and for the advancement of medicine and clinical care.

What information about me may be collected, used or shared with others?

The following personal health information will be collected, used for research and may be disclosed (shared with others) during your involvement with this research study:

- Name
- Address
- Telephone number
- Electronic mail address
- Medical record number
- Social security number (for payment)
- Personal and family medical history
- Allergies
- Current and past medications or therapies
- Information from a physical examination that generally also includesblood pressure reading, heart rate, breathing rate, and temperature
- Blood tests
- Urine tests

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- Weight
- Height
- Waist circumference
- Questionnaires

Why is my information being used?

Your information is used by the research team to contact you during the study. Your information and results of tests and procedures are used to:

- do the research
- oversee the research
- to see if the research was done right
- to evaluate and manage research functions.

Who may use and share information about me?

The following individuals may use or share your information for this research study:

- The Principal Investigator and the research team associated with the study
- The University of Pennsylvania Institutional Review Board (the committee responsible for overseeing research on human participants) and the University of Pennsylvania Office of Regulatory Affairs
- The University of Pennsylvania Office of Human Research (the office which monitors research studies)
- Authorized members of the University of Pennsylvania Health System and School of Medicine workforce who may need to access your information in the performance of their duties (for example: to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.)
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of the School of Medicine, might receive my information?

- Personnel from the National Institute of Diabetes and Digestive and Kidney Diseases, who sponsors the study
- The Office of Human Research Protections
- The study data and safety monitoring officer

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Once your personal health information is disclosed to others outside the School of Medicine, it may no longer be covered by federal privacy protection regulations.

The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

How long may the School of Medicine use or disclose my personal health information?

Your authorization for use of your personal health information for this specific study does not expire.

Your information may be held in a research database. However, the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization
- The University of Pennsylvania's Institutional Review Board grants permission as permitted by law

Can I change my mind about giving permission for use of my information?

Yes. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the investigator for the study. If you withdraw your permission, you will not be able to stay in this study.

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

You will be given a copy of this Research Subject HIPAA Authorization describing your confidentiality and privacy rights for this study.

By signing this document you are permitting the School of Medicine to use and disclose personal health information collected about you for research purposes as described above.

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Electronic Medical Records and Research Results

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

A clinical trial management system (CTMS) is used to register your information as a participant in a study and to allow for your research data to be entered/stored for the purposes of data analysis and any other required activity for the purpose of the conduct of the research.

If you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, information related to your participation in the research (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS. Information related to your participation in clinical research will also be contained in the CTMS.

If you have never received care within UPHS and are participating in a University of Pennsylvania research study that uses UPHS services, an EMR will be created for you for the purpose of maintaining any information produced from your participation in this research study. The creation of this EMR is required for your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility (i.e. your name, the name of your primary doctor, the type of insurance you have). Information related to your participation in the study (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in this EMR.
Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc.).

Once placed in your EMR or in the CTMS, your information may be accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc.).

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigators listed on page one of

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this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

Name of Subject (Please Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Please Print)	Signature	Date

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