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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

Participant Name: _____ Date: _____

STUDY TITLE: Urea for Chronic Hyponatremia: A Pilot Study

PRINCIPAL INVESTIGATOR: Helbert Rondon Berrios

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SOURCES OF SUPPORT: National Institutes of Health (NIH)/National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

SUMMARY OF THE RESEARCH

The purpose of this research study is to investigate how a dietary supplement called Urea affects people who have chronic low blood sodium levels. Urea is a substance that can be created in a lab but is also created by your liver when it processes protein you eat. Urea enters your blood stream and is filtered out of the body by your kidneys forcing some water out. In this way it may have an effect on the water in your body and possibly sodium levels.
"Investigational" means that the dietary supplement being tested has not been approved by the U.S. Food and Drug Administration (FDA) for the treatment of hyponatremia. As part of this study, you will be asked to restrict your fluid intake and take Urea (a powder that is dissolved in water). You will be assigned by chance (like a flip of a coin) to receive Urea either during the first part or the last part of your participation in the study. The total duration of your participation in the study is approximately 94 days and involves 9 study visits between the UPMC Kidney Clinic in Oakland and the Neuromuscular Research Laboratory in the South Side. During the study visits, the study team will perform the following activities: review your medical records, ask questions to determine whether you are experiencing side effects from Urea and how well you are able to tolerate it, test your reaction and decision making using specialized software on a tablet computer, test your balance while standing on a specialized piece of equipment, and draw blood and collect urine samples to measure sodium levels and other electrolytes.

REASONABLE, FORESEEABLE RISKS AND DISCOMFORTS

Risks and side effects related to Urea include those which are:

Likely: Distaste
Less Likely: Nausea, vomiting, diarrhea, and headaches
Rare but serious: None

REASONABLE, EXPECTED BENEFITS

There will be no direct benefit to you from participating in the study. However, this study will help doctors learn more about the use of Urea for hyponatremia (low blood sodium level) and it is hoped that this information will help in the treatment of future patients with conditions like yours.

ALTERNATIVE PROCEDURES TO COURSE OF TREATMENT, IF ANY

You may choose not to participate in this study. If this is your decision, there are other choices such as being referred to see a specialist to treat your hyponatremia (low blood sodium level) where you might receive Urea outside of this study. You may discuss these options with your primary care doctor.

INTRODUCTION

You are being asked to take part in a research study that is being funded by the National Institutes of Health. Before you decide to take part, it is important for you to know why the research is being done and what it will involve, including any potential risks to you as well as any potential benefits you may receive.

Read the information below closely, and discuss it with family and friends if you wish. Ask one of the study staff if there is anything that is not clear or if you would like more details. Take your time to decide. If you do decide to take part, your signature on this consent form will show that you received all of the information below, and that you were able to discuss any questions and concerns you had with a member of the study team.

BACKGROUND AND PURPOSE

The purpose of this pilot research study is to evaluate how a dietary supplement called Urea can be used to treat hyponatremia (low blood sodium level). Hyponatremia is a common problem and many patients with hyponatremia suffer from difficulty with attention as well as balance problems. We do not know if raising blood sodium level actually helps to prevent the complications associated with hyponatremia. We also don't know what the best treatment is to increase the blood sodium level. With this pilot research study, we hope to learn more about whether Urea is safe to take, whether patients can tolerate taking Urea for several weeks, whether Urea increases blood sodium level, and whether Urea can help prevent the complications associated with low blood sodium level. We intend to use the results of this pilot research study to design a larger study in the future to definitely test whether Urea is beneficial for patients with hyponatremia.

DURATION OF THE RESEARCH

The total duration of this study is 2 years. However, your participation will only last a total of approximately 94 days beginning at the time of your first study visit.

RESEARCH ACTIVITIES
If you decide to take part in this study, this is what will happen:

Screening visit:

- You will come in person to the UPMC Kidney Clinic
- We will obtain informed consent from you to enroll you in the study.
- If your doctors started you on urea, we will ask their permission to stop urea. Then we will arrange for a screening visit within 5 to 7 days after you stop urea. This visit will be at the UPMC Kidney Clinic. If your doctor does not give permission to stop urea after you sign consent, you will be withdrawn from the study with no further follow up.
- Alternatively, if you are admitted, we will obtain informed consent while you are in the hospital. After you sign consent, if your doctors started you on urea in the hospital, we will ask their permission to stop urea. Then we will arrange for a screening visit within 5 to 7 days after your discharge from the hospital. This visit will be at the UPMC Kidney Clinic. If your doctor does not give permission to stop urea after you sign consent, you will be withdrawn from the study with no further follow up.
- We will perform a focused physical examination which includes:
  - Assessment of your ability to walk normally without help
  - Assessment of your memory, concentration, and ability to follow instructions
  - Assessment of the presence of excess fluid in your body.
- We will draw approximately 14 mL (about 1 tablespoon) of your blood and send it to the laboratory for analysis.
- One of the blood tests is for your cortisol level. Cortisol is a hormone made by your adrenal glands that affects your response to stress and inflammation. If the level is low in your blood, we will ask you to come to UPMC Montefiore Clinical Translation Research Center (UPMC MUH-CTRC) for an outpatient visit. We will do further testing to be sure you are eligible for the study.
- We will ask you to provide a urine sample and send it to the laboratory for analysis.
- If you are a woman of childbearing potential, we will also perform a urine pregnancy test.
- This visit will last approximately 1.5 hours

Phone call to confirm enrollment in the study: Based on the results of your screening physical exam and laboratory test results we will call you to inform you if you can participate in the study. If you are eligible to participate we will mail you a container with instructions to collect your urine for 24 hours. We will ask you to start the urine collection after you wake up the day before your first study visit and bring this container to the visit. If your screening physical exam and/or laboratory test indicate that you are not eligible to participate, then we will inform you that you cannot be enrolled in the study and will give you the choice to follow up in the UPMC kidney clinic for the management of your hyponatremia.

PERIOD 1

First study visit (Day 0 of Period 1)

- You will to come in person to the University of Pittsburgh Neuromuscular Research Laboratory located at 3860 S Water St, Pittsburgh, PA 15203.
- You will bring the container with the 24-hour urine collection you started the day prior.
- We will draw approximately 14 mL (about 1 tablespoon) of your blood and send it to the laboratory for analysis
- We will give you a survey to complete that takes approximately 5 minutes. The survey asks for your views about your health. This will help us keep track on how you feel and how well you are able to do your usual activities.
- We will test your reactions and decision making using specialized software on a tablet computer.
- We will test your balance while standing on a specialized piece of equipment. You will be asked to stand on both legs on top of a platform in a dynamic moving environment. You will go through six conditions, with three trials per condition, lasting about 20 seconds each. You will be asked to look forward, and stand as motionless as possible with your arms at your sides. The six conditions include the possibility of moving surroundings or moving base of support. If you move or lose your balance during the procedures, you will be asked to repeat that part again. You will be supported by means of a harness in the equipment to make sure you cannot fall over while performing the tests.
- You will be asked to restrict your fluid intake to no more 1200 mL/day for approximately the next 42 days. This includes all fluids such as water, juice, soda, soup, coffee, tea, etc. A diary to record your daily fluid intake will be provided at this time.
- If you are randomized to take urea early in your participation in the study then you will be given 48 urea powder pouches with instructions on how to take the urea every day. A diary to record your daily urea intake will be provided at this time.
- This visit will last approximately 2.5 hours.

Second study visit (Day 7 of Period 1)

- We will call you on the phone to ask you some questions about any new symptoms you might have experienced since your last visit.
- You will go to the UPMC laboratory of your choice that day to have your blood drawn for analysis.
- If you are taking urea, we might call you on the phone again to ask you to change the dose of urea depending on your sodium level results.
- This visit will last approximately 20 minutes.

Third study visit (Day 14 of Period 1)

- We will call you on the phone to ask you some questions about any new symptoms you might have experienced since your last visit.
- You will go to the UPMC laboratory of your choice that day to have your blood drawn for analysis.

- We will give or mail you a container to collect your urine for 24 hours and bring it in your next visit. You should start the collection the day prior to your next visit.
- If you are taking urea then we will give you and/or mail you more urea powder pouches as needed to complete your participation in period 1 of the study.
- If you are taking urea, we might call you on the phone again to ask you to change the dose of urea depending on your sodium level results and have your blood drawn again in approximately 7 days.
- This visit will last approximately 30 min.

Reminder phone call
We will call you 48-72 hours before your next study visit to remind you of your upcoming visit.

Fourth study visit (Day 42)
- You will to come in person to the University of Pittsburgh Neuromuscular Research Laboratory located at 3860 S Water St, Pittsburgh, PA 15203.
- You will bring the container with a 24-hour urine collection you started the day prior.
- We will draw approximately 14 mL (about 1 tablespoon) of your blood and send it to the laboratory for analysis
- We will ask you some questions about any new symptoms you might have experienced since your last visit.
- If you had been taking urea then we will ask you a few questions about your acceptability of urea. We will also ask you to discontinue urea at this time and return the urea powder pouches that you did not use.
- We will give you a survey to complete that takes approximately 5 minutes. The survey asks for your views about your health. This will help us keep track on how you feel and how well you are able to do your usual activities.
- We will test your reactions and decision making using specialized software on a tablet computer.
- We will test your balance while standing on a specialized piece of equipment. You will be asked to stand on both legs on top of a platform in a dynamic moving environment. You will go through six conditions, with three trials per condition, lasting about 20 seconds each. You will be asked to look forward, and stand as motionless as possible with your arms at your sides. The six conditions include the possibility of moving surroundings or moving base of support. If you move or lose your balance during the procedures, you will be asked to repeat that part again. You will be supported by means of a harness in the equipment to make sure you cannot fall over while performing the tests.
- You will be asked to stop the fluid restriction until your next visit.
- You will be asked to return the diaries of fluid and urea intake for Period 1 at this time.
- We will give you a container to collect your urine for 24 hours and bring it in your next visit. You should start the collection the day prior to your next visit.
- This visit will last approximately 2.5 hours.

Following Period 1, you will have approximately a 10-day washout period before starting Period 2. "Washout period" refers to an amount of time that you will not take the study drug, so that it can wash out of your system.

PERIOD 2

Fifth study visit (Day 0 of Period 2)

- You will to come in person to the University of Pittsburgh Neuromuscular Research Laboratory located at 3860 S Water St, Pittsburgh, PA 15203.
- You will bring the container with the 24-hour urine collection you started the day prior.
- We will draw approximately 14 mL (about 1 tablespoon) of your blood and send it to the laboratory for analysis
- We will give you a survey to complete that takes approximately 5 minutes. The survey asks for your views about your health. This will help us keep track on how you feel and how well you are able to do your usual activities.
- We will test your reactions and decision making using specialized software on a tablet computer.
- We will test your balance while standing on a specialized piece of equipment. You will be asked to stand on both legs on top of a platform in a dynamic moving environment. You will go through six conditions, with three trials per condition, lasting about 20 seconds each. You will be asked to look forward, and stand as motionless as possible with your arms at your sides. The six conditions include the possibility of moving surroundings or moving base of support. If you move or lose your balance during the procedures, you will be asked to repeat that part again. You will be supported by means of a harness in the equipment to make sure you cannot fall over while performing the tests.
- You will be asked again to restrict your fluid intake to no more 1200 mL/day for approximately the next 42 days. This includes all fluids such as water, juice, soda, soup, coffee, tea, etc. A new diary to record your daily fluid intake will be provided at this time.
- If you are randomized to the take urea late in your participation in the study then you will be given 48 urea powder pouches with instructions to the take the urea every day for approximately the next 42 days. A new diary to record your daily urea intake will be provided at this time.
- This visit will last approximately 2.5 hours

Sixth study visit (Day 7 of Period 2)

- We will call you on the phone to ask you some questions about any new symptoms you might have experienced since your last visit.
- You will go to the UPMC laboratory of your choice that day to have your blood drawn for analysis.
- If you are taking urea, we might call you on the phone again to ask you to change the dose of urea depending on your sodium level results.
- This visit will last approximately 20 minutes.

Seventh study visit (Day 14 of Period 2)

- We will call you on the phone to ask you some questions about any new symptoms you might have experienced since your last visit.
- You will go to the UPMC laboratory of your choice that day to have your blood drawn for analysis.
- We will give or mail you a container to collect your urine for 24 hours and bring it in your next visit. You should start the collection the day prior to your next visit.
- If you are taking urea then we will give you and/or mail you more urea powder pouches as needed to complete your participation in period 1 of the study.
- If you are taking urea, we might call you on the phone again to ask you to change the dose of urea depending on your sodium level results and have your blood drawn again in approximately 7 days.
- This visit will last approximately 30 min.

Reminder phone call

- We will call you 48-72 hours before your next study visit to remind you of your upcoming visit.

Eight study visit (Day 42 of Period 2)

- You will to come in person to the University of Pittsburgh Neuromuscular Research Laboratory located at 3860 S Water St, Pittsburgh, PA 15203.
- You will bring the container with a 24-hour urine collection you started the day prior.
- We will draw approximately 14 mL (about 1 tablespoon) of your blood and send it to the laboratory for analysis
- We will ask you some questions about any new symptoms you might have experienced since your last visit.
- If you had been taking urea then we will ask you a few questions about your acceptability of urea. We will also ask you to discontinue urea at this time and return the urea powder pouches you did not use.
- We will give you a survey to complete that takes approximately 5 minutes. The survey asks for your views about your health. This will help us keep track on how you feel and how well you are able to do your usual activities.
- We will test your reactions and decision making using specialized software on a tablet computer.
- We will test your balance while standing on a specialized piece of equipment. You will be asked to stand on both legs on top of a platform in a dynamic moving environment. You will go through six conditions, with three trials per condition, lasting about 20 seconds each. You will be asked to look forward, and stand as motionless as possible with your arms at your sides. The six conditions include the possibility of moving surroundings or moving base of support. If you move or lose your balance during the procedures, you will be asked to repeat that part again. You will be supported by means of a harness in the equipment to make sure you cannot fall over while performing the tests.

- You will be asked to stop the fluid restriction.
- You will be asked to return the diaries of fluid and urea intake for Period 2 at this time.
- This visit will last approximately 2.5 hours.

POSSIBLE RISKS OR DISCOMFORTS

Any procedure has possible risks. The procedures in this study may cause all, some or none of the risks or side effects listed. Rare, unknown, or unforeseeable (unanticipated) risks also may occur.

Urea: The risks of oral urea include bad taste in your mouth, nausea, upset stomach, and headaches. You will be monitored for these complications while you are receiving urea. These complications occur very infrequently. If you develop one or more of these complications, we first will ask you to monitor your symptoms. If your symptoms persist beyond 24 hours then we will decrease the dose of urea. If the symptoms still persist beyond 72 hours then we will discontinue the urea. It is unclear whether oral urea can have negative effects on pregnancy. Therefore, females should not get pregnant while in the study. Highly effective forms of contraception include: intrauterine device (IUD), oral contraceptives, injectable progesterone, sub-dermal implant, or a diaphragm with spermicide and condom.

Fluid restriction: The main risk is feeling thirsty.

Blood drawing: It may cause pain and a bruise. Some people may become light-headedness (dizzy) or faint after blood drawing. There is also a rare risk of infection at the site of the blood draw.

Balance tests: There is a risk of falling while undertaking the balance testing, and this is heighted with increased age. To minimize this risk, we ensure that the participants are strapped into a harness which will catch them if they lose their balance.

Reaction and decision making tests: There are no risks involved with these tests.

Medical records review: There is a risk of breach of confidentiality.

Discontinuing clinically prescribed urea: This might cause the blood sodium level to decrease. To minimize this risk, we will first obtain approval from the participant's treating physician to make sure is safe to do so and schedule participants for the screening visit within 5-7 days to ensure a blood sodium level will be checked after urea discontinuation. In addition, we are only enrolling participants with a blood sodium level no lower of 125 mmol/L where the risk of experiencing any symptoms related to low blood sodium is very low.

POTENTIAL BENEFITS

You may not get any direct benefits from taking part in this research study. However, the information we get from this study will help us be able to better care for patients with hyponatremia in the future.

ALTERNATIVE TREATMENTS

You may choose not to participate in this study. If this is your decision, there are other choices such as being referred to see a specialist to treat your hyponatremia. You can receive urea outside of this study. You may discuss these options with your primary care doctor.

NEW INFORMATION

Sometimes during the course of a research study, new information becomes available about the prevention of complications of hyponatremia that could change your willingness to continue in the study. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw at that time, your research doctor will make arrangements for your medical care to continue. If you decide to continue in the study, you may be asked to sign an updated consent form. Your research doctor could also decide it to be in your best interests to withdraw you from the study. He or she will explain the reasons and arrange for your usual medical care to continue. After the study is completed, the results of the study will be conveyed to you.

PRIVACY AND CONFIDENTIALITY

Taking part in this study will involve collecting private data about you. This data will be protected in the following ways:

All forms generated as part of this study will be locked in filing cabinets. Data will be entered on computers that are protected with passwords. Only approved study personnel will have access to these data.

Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

Your data will be combined with data from other people taking part in the study. We will write about the combined data we have gathered. Any talks or papers about this study will not identify you.

Your name, date of birth, address, telephone numbers,Social Security Number as well as the contact information of your secondary and emergency contact will be maintained in a secure file in the study database and will be only accessible to specific members of the study team. They will be used only as necessary within UPMC or when there is a need to check your non-UPMC hospitalizations during the study. If you are hospitalized at a non-UPMC hospital, medical information from your hospitalization may be requested. If you have an adverse experience during the course of the study, your entire medical record may be used and disclosed as clinically necessary as well as pursuant to federal and state laws and regulations.

In addition to the investigators listed and their research staff, the following individuals may have access to your information related to your participation in this research study:

- Authorized representatives of the study sponsor, federal regulatory agencies, and the University of Pittsburgh Office of Research Protections may review your identifiable research information for purposes of monitoring the conduct of this research study.
- If investigators learn that you, or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.
- Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to your identifiable information to provide services and addressing billing and operational issues.
- The data, samples, and genetic data generated from samples may be shared with other researchers and with federal repositories, in a de-identified manner without additional informed consent.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained above. The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Research records will be maintained for at least 7 years following final reporting or publication of a project.

FDA CLINICAL TRIAL REGISTRY [21 CFR 50.25]

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

COSTS

You will not be charged for any treatments or procedures that are part of this study.

PAYMENTS

You will receive $20 per study visit (total of $180 over 9 study visits) for your participation in this study. In addition, when parking is not free, your parking to attend study visits will be paid for.

All compensation is taxable income to the participant regardless of the amount. If a participant receives $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding'; thus you would only receive 76% of the expected payment.

CLINICAL RELEVANT RESULTS:

You may be individually notified of clinically relevant results. For instance, your memory, concentration, and ability to follow directions will be tested. If the results of this assessment are low, we will notify you and your PCP of this result. If there are results from the blood work we do for the study that would affect your clinical care, we will inform you. We will discuss follow up care with you if needed.

COMPENSATION FOR INJURY

If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not, however, waive any legal rights by signing this form.

VOLUNTARY PARTICIPATION

Your participation in this research study is entirely voluntary. You may want to discuss this study with your family and friends and your personal physician before agreeing to participate. If there are any words you do not understand, feel free to ask us. The investigators will be available to answer your current and future questions.

Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

As both your doctor and a research investigator, he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is

not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor.

You can, at any time withdraw from this research study. This means that you will also be withdrawn from further participation in this research study. Any identifiable research or medical information obtained as part of this study prior to the date that you withdrew your consent will continue to be used and disclosed by the investigators for the purposes described above.

If you decide to withdraw from study participation after you have received the study drug, you should participate in additional monitoring follow-up procedures that are being conducted to measure the safety of the study drug.

It is possible that you may be removed from the research study by the researchers without your consent for reasons such as: it will be in your best interest; you do not follow the study plan; or you experience a study-related injury.

Investigator may request follow-up for safety reasons: If you are withdrawn from participation in this research study, you will asked to follow up in the UPMC Kidney Clinic for monitoring of your blood sodium level.

To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.

HIPAA AUTHORIZATION FOR DISCLOSURE OF PROTECTED HEALTH INFORMATION (PHI)

As part of this research study, we are requesting your authorization or permission to review your medical records to determine whether you meet the conditions for participation in this study, to compare your earlier test results to the findings from this study, and if possible, to use your previous exam results in place of, or in addition to, some of the exams needed for this study.This authorization is valid for an indefinite period of time. We will obtain the following information: name, address, telephone numbers, Social Security Number, medical record number, past medical history, hospitalizations, medications that you are taking, and results of laboratory tests, imaging tests and medical procedures.

Results of screening, planned or possible follow up laboratory tests done by UPMC laboratory for the purpose of the study will be entered in your UPMC medical record. If you require a visit at the UPMC MUH-CTRC for additional screening, the details will be entered in your UPMC medical record.

This identifiable medical record information will be made available to members of the research team for an indefinite period of time.

Your medical information, as well as information obtained during this research study, may be shared with other groups, possibly including authorized officials from the study sponsor, federal regulatory agencies, and the University of Pittsburgh Office of Research Protections, for the purpose of monitoring the study. Authorized representatives of UPMC or affiliated health care providers may also have access to this information to provide services and addressing billing and operational issues.

We will protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University.

You can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up that point will continue to be used by the research team.

QUESTIONS ABOUT THE STUDY

You can contact the study investigator if you have any questions about the study, concerns or complaints. Contact study coordinator Rachel Cohen at phone number 724-271-8595. If you have any questions about your rights as a research subject or wish to talk to someone other the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.

CONSENT TO PARTICIPATE

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given.

I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation.

By signing this form, I agree to participate in this research study and provide authorization to share my medical records. A copy of this consent form will be given to me.

_____ _____

Participant's Printed Name Date

_____
Participant's Signature

INVESTIGATOR CERTIFICATION

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____ _____
Printed Name of Person Obtaining Consent Role in Research Study

_____ _____
Signature of Person Obtaining Consent Date