RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title: Physiological effects of ANGPTL3 variants humans

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Research Study Summary for Potential Subjects

You are being invited to participate in a research study. Your participation is voluntary, and you should only participate if you completely understand what the study requires and what the risks of participation are. You should ask the study team any questions you have related to participating before agreeing to join the study. If you have any questions about your rights as a human research participant at any time before, during or after participation, please contact the Institutional Review Board (IRB) at (215) 898-2614 for assistance.

The purpose of this study is to determine how changes in the genetic code of a protein called ANGPTL3 may affect the levels of cholesterol and other fats, the levels of glucose in the blood, and the risk of heart disease and diabetes. Both people that have these changes and people that do not can participate in this study.

If you agree to join the study, you will be asked to complete the 3 visits: 1. A screening visit to determine to see if you are eligible. 2. An inpatient visit that requires that you remain in the research unit for 2 nights and 1 day. During this visit you will receive an infusion and 18 blood draws will be collected over time. 3. A visit that requires that you remain in the research center all day. During this visit you will be asked to drink a milkshake made of heavy cream and several blood draw will be collected. More details of the research procedures can be found in the “What am I being asked to do?” section, starting at page 4.

Your participation will last about 1-2 months, depending on when the 3 visits are completed.

You are not expected go get any benefit from being in this research study. Your participation in the study may help us better understand how the body handles cholesterol. The most common risks and discomforts are associated to the long stays in the research unit, the IV line that will be inserted in your veins during the infusion and the blood draws, and the risk of nausea or diarrhea after drinking the milkshake.

Please note that there are other factors to consider before agreeing to participate such as other procedures, use of your personal information, costs, and other possible risks not discussed here. If you are interested in participating, a member of the study team will review the full information with you. You are free to decline or stop participation at any time during or after the initial consenting process.

Why am I being asked to volunteer?

You are being invited to participate in a research study because you have levels of lipids (cholesterol or other fats) that may be due to changes in the genetic code. Your participation may help us to better understand how our body transports cholesterol and other fats which can contribute to risk factors seen in heart disease and diabetes.

Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no 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 research team is going to talk to you about the research study, and they will give you this consent form to read.

You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the investigator and/or the research team about anything you do not understand. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

The purpose of this study is to determine how changes in the genetic code of a protein called ANGPTL3, may affect the levels of cholesterol and other fats, the levels of glucose in the blood, and the risk of heart disease and diabetes. All humans are born with many changes in their genetic code (called genetic variants), most of which are harmless. Certain variants may be linked with changes in lipids levels.

“Lipids” (cholesterol and other fats) circulate in the bloodstream in particles called “lipoproteins”. You may have heard of the lipoproteins named HDL (“good” cholesterol) and LDL (“bad” cholesterol). Their levels in your blood depend on many factors that regulate their production and breakdown. One of these factors is the protein called ANGPTL3. To understand how this protein works, we will study people that have ANGPTL3 genetic variants and those that don’t. and compare their results.

Lipoproteins have three main components: proteins, cholesterol, and additional lipids, such as “triglycerides”. To study what happen to the lipoproteins circulating in the blood stream, we will “tag” their components with different “tracers”.

A tracer is an extremely small amount of a substance that can be used to follow events in the body. We use a substance called “leucine” to tag proteins, a substance called “glycerol” to tag triglyceride and a substance called “acetate” to tag other lipids. Leucine, glycerol, and acetate are natural substances that are also present in your body.

Lipoproteins levels change with fasting and feeding. To study the effect of ANGPTL3 after having a fat meal, we will look at the levels of cholesterol and other fats before and after ingesting a fat-rich milkshake.

How long will I be in the study?

Participation in the study will involve three visits at the Center for Human Phenomic Science (CHPS), the clinical research center at the University of Pennsylvania. The first visit, known as the "screening visit," lasts about 4 hours. The second visit, the "kinetic study visit," may last for two nights and one day. The third visit, the "OFTT study visit" may last up to 10 hours. Your participation in the study ends once you have completed the study visit.

We plan to enroll up to 30 subjects by screening up to 50 participants. The University of Pennsylvania is the only study site.

What am I being asked to do?

Visit 1 (screening visit)

The purpose of this visit is to explain the study to you and see if you meet the requirements to be in the study.

Please do not have anything to eat or drink (except water) for at least 12 hours before your visit.

We will explain the study to you and respond to any questions you may have. If you decide to participate, you will be asked to sign this informed consent form.

We will ask you questions about your medical and family history, and the medications you are now taking and have taken within the last 30 days. We will review the questionnaire with you. If you have been a patient at Penn Medicine, an authorized member of the study team may look at your electronic medical record (EMR) to help complete or update your health questionnaire information.

We will take your vital signs (height, weight, blood pressure, heart rate, and temperature) and collect blood (about three tablespoons) and urine samples for laboratory tests. If you are female and could become pregnant, a urine pregnancy test will be done. The pregnancy test has to be negative in order for you to participate in the study.

Your blood and urine samples will be used to run routine safety tests and a lipid panel. A sample of blood will also be collected for genetic testing to see if you carry a genetic variant for ANGPTL3 or other genes that may determine the levels of cholesterol and other lipids.

You will be asked to complete an Oral Glucose Tolerance Test. This test is done to study your body's response to glucose (sugar). To do this, a small tube (an "intravenous catheter", or "IV") will be placed in a vein in your arm to reduce discomfort and to allow for easier blood collection. Then, you will be given about 8 ounces of a sugar solution to drink. We will then take blood samples over the next two hours every 30 minutes after drinking the sugar solution. A total of less than 10 mL of blood (about 2/3 of a tablespoon) will be drawn for this test.

You will be contacted afterwards to tell you if you meet all of the criteria to continue in the study and to schedule the study visit.

Kinetic study visit

You will be asked to come to the inpatient CHPS location at around 6:00 p.m. for the study visit. This visit will last two nights and one day.

We will ask you about any changes in your medical history and medications since your screening visit or your prior visit for one of our research studies. We will also ask you about any problems you have experienced and any unusual or unpleasant feelings you may have had since your last visit.

We will take your vital signs (weight, blood pressure, heart rate, and temperature) and your waist and hip circumference. A brief physical exam will be done. If you are female and could become pregnant, a urine pregnancy test will be done. The pregnancy test has to be negative in order for you to participate in the study. Afterwards, you will be provided with dinner and will then have nothing to eat or drink (except water) for the remainder of the night.

You may also have the option to be admitted in the morning. If you are interested in this option, you should discuss it with the study team. If you do come in for your visit in the morning, you will be asked to follow specific dietary instructions at home for dinner and to then have nothing to eat or drink (except water) after this meal. You will need to arrive prior to 6:00 a.m. in this case all the procedures described above will be performed before starting the “lipoprotein kinetics” portion of your visit.

During this portion of the visit, you will be provided up to 20 small, identical meals. These meals will be served starting approximately at 6:00 a.m., and then one meal each hour for the next 19 hours. Your last meal will be served at around 1:00 a.m.

Around the same time as your first meal, a small IV will be placed in a vein in your arm to reduce discomfort and to allow for easier blood collection. A second small IV will be placed in a vein in your other arm. About 3 hours after your first small meal (around 9:00 a.m.), you will be given a saline solution through the second IV containing the tracer(s) (leucine, glycerol, and acetate) used to tag the lipoproteins. The solution will flow into your vein through the IV for a 15-hour time period. Blood will be drawn before, during and after the 15-hour-long infusion. We will draw up to 18 blood samples.

After the blood draw taken the following morning (Study day 2), you will receive a small amount of a blood thinning medication called heparin. After 10 minutes, a small amount of blood (2 tubes, about 1 tablespoon) will be taken. After this blood draw, you will be asked to remain at the center for about 30 min more. We will provide you with breakfast and make sure that you are fine before you leave.

You will be asked to come back the following morning for a small blood draw.

The total amount of blood taken is about 1 cup. This is less than the amount you would give in a Red Cross blood donation.

OFTT study visit

OFTT stands for "oral fat tolerance test". This test is done to study how your body processes fats after you drink a glass of milkshake made with heavy cream. Because we are using cream, you must tell us if you cannot ingest milk products.

We will ask that you do not have anything to eat or drink (except water) for 12 hours before your visit. You will spend most of the day at the research unit (about 10-12 hours). After you arrive, we will take your vital signs (blood pressure, heart rate, weight, height, and temperature) and place a small IV. Before and after drinking the heavy cream, we will draw blood out of the IV every hour for the first 6 hours, and then every 2 hours until completion of the test. We will also regularly check your vital signs.

Each time we take a sample, we will collect up to 10 mL of blood (2/3 of a tablespoon). This amounts up to 90mL (about 6 tablespoons for the entire oral fat tolerance test). Throughout the day, you may drink water and no-calorie, non-caffeinated drinks, but you will not be allowed to eat (because food interferes with the test). We will provide a meal after you complete the test.

Research Samples

Some of the blood samples that are taken during the study visits may be used in the future for research related to this study or other studies to investigate how the cholesterol and glucose levels are regulated. This research may include the isolation of genetic material for genetic analysis, and the isolation of blood cells for creation of "cell lines" that can be grown in the laboratory, stored and studied in the future.

Neither your name nor your medical record number will appear on the research samples. A study ID and the date the specimen is drawn will be the only information on the label. You will not be informed of the results of the research performed on research samples.

DNA and/or cells created from the blood samples you have donated will be used by Dr. Cuchel and her study team and may be shared with researchers both inside and outside of Penn. The researchers will be given the DNA, data and/or cells without any potentially identifying information. Information gained from research on your DNA and/or cells may be used for the development of diagnostic procedures or new treatments for major diseases. Your DNA and/or cells will not be sold to any person, institution, or company for financial gain or commercial profit. Neither you nor your heirs will gain financially from discoveries made using the information and/or specimens that you provide.

Below is a table that summarizes the visit-specific procedures of the study.

	Screening Visit	Kinetic Visit	OFFT Visit
Procedure			
Informed Consent	X		
Medical History, Adverse Events, Concomitant Medications	X	X	X
Physical Exam	X		
Vitals, Waist Circumference, Weight, Height	X	X	X
Blood Draw	X	X	X
Oral Glucose Tolerance Test	X		
2-Night Inpatient Admission		X	
Stable Isotopes Infusion and blood draws		X	
Post-Heparin Sample		X	
Oral Fat Tolerance Test			X
Genetic Confirmation	X		
Urine Pregnancy Test (females of childbearing potential only)	X	X	

What are the possible risks or discomforts?

There are some potential risks and discomforts that may occur as part of the study:

- Possible risks or discomforts caused by the blood draw and IV catheter: With any blood test, there may be some minor discomfort, bruising, swelling and/or fainting associated with the drawing of blood. There is also a very small chance (less than 1%) of infection at the needle puncture site. While a catheter is in your vein, it is typically painless, but it can result in some swelling, discomfort, faintness, bruising, or bleeding at the site of puncture. There is also a very small chance (less than 1%) of infection at the site and the formation of a little blood clot at the end of the catheter so that blood cannot be drawn out through it. If this were to happen, the catheter would need to be removed and a new one placed at a different location.

- Possible risks or discomforts caused by fasting: Fasting does not result in medical problems in most people. However, there are some people who have medical conditions that limit their ability to tolerate a fast. If your doctor has told you that you should not fast, we will ask you not to participate in the study. Please tell us if you think you might have a problem with fasting.
- Possible risks or discomforts caused by Oral Glucose Tolerance Test (OGTT): The known risks for OGTT are minimal and include lightheadedness as well as bruising, pain, and infection at the IV site.

- Possible risks or discomforts caused by the tracer solution: There is the possibility that the solution containing the tracer may be contaminated and may cause an infection or you to have flu-like symptoms. This possibility is unlikely, as an experienced pharmacist will prepare the solution. He or she will make sure that the solution is sterile and suitable to be injected.

- Possible risks or discomforts caused by heparin: Heparin is used clinically as a blood thinner to prevent or reduce blood clotting. The use of heparin is also a well-established method to study lipases, proteins that help clear fats from circulations. The dose of heparin that you will receive (60 units/kg body weight) is lower than the typical dose that is given clinically for blood thinning purposes. This dose can partially thin the blood for up to 4 hours, and therefore if you receive heparin as part of this study there is a slight increased risk of bleeding. To minimize this risk, you will not be asked to participate in this part of the study if you have a history of anemia or bleeding problems. You will also be asked to remain in the research unit for at least 30 min after you receive heparin and not to participate in any contact sports for at least 4 hours after.

- Possible risks or discomforts caused by Oral Fat Tolerance Test (OFTT): If you are allergic to milk products or if you have severe lactose intolerance, you will not be able to participate in this study visit. Because the milkshake that you need to ingest contains heavy cream, there is a small risk of nausea, vomiting, and/or diarrhea. Because you will not be eating for the duration of the test, there is a risk of your feeling faint at the end of the test. To minimize this risk, we will give you a meal at the end of your test and check to make sure that you are steady on your feet before you leave. You will not be permitted to participate in this part of the study if you are allergic to milk, or if you have severe lactose intolerance. Please inform study team if you are unable to tolerate an 8-ounce glass of milk even with lactase replacement (LACTAID).

- Possible risks of genetic testing: This research includes genetic testing. Even without your name or other identifiers, your genetic information is unique to you. We believe the chance that someone will identify you is very small, because we will use a code to label your sample and your personal information (name, address, telephone number, date of birth) will not be attached to the blood samples or genetic data used for this research. However, the risk may change in the future as people come up with new ways of tracing information.

  There can be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a research study. Even though your genes are unique, you share some of the same genes with your blood relatives. Although we are not able to know all of the risks from taking part in research on inherited traits, we believe that the risks to you and your family are very low, because your samples will be coded. Research results will not be returned to you or your doctor.

  Very rarely health or genetic information could be misused by employers, insurance companies, and others. For example, it could make it harder for you to get or keep a job or insurance, or life insurance companies may charge a higher rate based on this information. We believe the chance these things will happen is very small, but we cannot make guarantees.

  A federal law (Genetic Information Non-Discrimination Act, GINA) helps reduce the risk from health insurance or employment discrimination. The law does not include other types of

misuse by life insurance or long term care insurance. If you want to learn more about GINA, you can find information about it on the internet or ask the study staff.

- Possible risks for pregnancy and breast feeding: If you are a woman that is pregnant, breastfeeding or plans to become pregnant, you will not be able to participate in this study. Pregnancy and breast-feeding may alter the way your body handles cholesterol and lipoproteins. Although the kind of "tags" that we use should not pose any harm, it is also possible that harmful side effects that are not yet known could happen to both the mother and unborn or breastfeeding child. If you are currently pregnant, it is important that you inform the study team because you will not be able participate in the study. If you are able to become pregnant, you will be given a urine pregnancy test at the beginning of the study visit.

  It is important that you use an effective form of birth control (contraception) between the screening visit and your study visit if you are sexually active and may become pregnant. You may choose to use an occlusive cap (diaphragm or cervical/vault cap) or your male partner can use a condom combined with a spermicidal foam/gel/film/cream/vaginal suppository. The following methods are more effective and are also acceptable: (1) total abstinence from male/female intercourse, or (2) male/female sterilization, or (3) use of oral, injected or implanted hormonal methods of contraception (in case of oral contraception you should have been using the same pill on a stable dose for a minimum of 3 months before the study visit), or (4) placement of an intrauterine device (IUD) or intrauterine system (IUS).

There may be other unforeseeable risks that are not mentioned here.

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 go get any benefit from being in this research study. Your participation in the study may help us better understand the factors that affect the levels of cholesterol and other fats and the risk of heart disease and diabetes. .

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

The alternative to this study is not to participate. If you decide not to participate, your decision will not affect in any way your present or future care as a patient.

Will I be paid for being in this study?

In order to compensate you for your time and effort, you will have the possibility to receive up to $400: $50 for completion of screening visit, $250 for completion of the kinetics visit, and $100 for completion of the oral fat tolerance test. Parking will be provided free of charge at both the screening and study visits and reimbursement for reasonable expenses for public transportation will be offered.

You may have the option to receive payment through University of Pennsylvania ClinCard debit card, and the funds will be loaded on the card within 24 hours of each scheduled transaction. It is important that you do not lose the University of Pennsylvania debit card. Costs for replacing lost or stolen University of Pennsylvania debit cards will be your responsibility. The cost to replace the debit card is $3.90 and that amount will be deducted from your study visit payment. You can also have your payment transferred from debit card to mailed check.

Will I have to pay for anything?

There will be no cost to you for any visits or procedures required by this study. You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay.

Will I receive the results of research testing?

Most tests done in research studies are only for research and have no clear meaning for health care. Research results will not be returned to you because they would not be relevant to your health care. However, you can ask the study team to receive the safety tests and the lipid panel done at screening visits. These tests may also be placed in your medical records.

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

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 us 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 researcher's name and phone number are listed on the front page of the consent form.

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

This study is expected to end 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 PI, without your consent because:

- The Primary Investigator feels 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.
- The study Principal Investigator, or the Food and Drug Administration (FDA) has decided to stop the study.

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

CONFIDENTIALITY AND PRIVACY AUTHORIZATION

How will my personal information be protected during the study?

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. 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. The Institutional Review Board (IRB) at the University of Pennsylvania will have access to your records. If this study is being overseen by the Food and Drug Administration (FDA), they may review your research records.

All your study information, including tissue and/or fluid samples, will be kept confidential to the fullest extent possible. Your study information will be kept in a coded form and your name will not be attached. The research site will store the code in a safe place and only the study team will have access to this code. The research site will keep this code to maintain a link between your name and the information about you created and collected during this study.

Will information about this study be available to the public?

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you.

What may happen to my information and samples collected on this study?

Your samples may be used to create products, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family. There are no plans to tell you about any of the specific research that will be done. Whole genome sequencing will not be conducted on your samples. Whole genome sequencing involves analyzing your entire personal genetic code.

Future Use of Data and/or Specimens

Your information and samples will be de-identified. De-identified means that all identifiers have been removed. The information and samples could be stored and shared for future research in this de-identified fashion. It would not be possible for future researchers to identify you as we would not share any identifiable information about you with future researchers. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information and samples only applies to the information and samples collected on this study.

Electronic Medical Records and Research Results

What is an Electronic Medical Record and/or a Clinical Trial Management System?

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.).

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

- Name
- Address, including e-mail
- Demographics: Race, Sex, Birth date
- Telephone number
- Social security number (only to provide compensation)
- Medical Record Number and information from your medical records
- Allergies
- Current and past medications or therapies
- Information from information from past tests and procedures
- Information from past medical and medicine history and family medical history

There may be other information that may be used and given to others that has not been stated above. It is advised that you discuss this with the study staff and ask any questions that you may have about the sharing of your health information.

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
- see if the research was done right
- 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 study team; and authorized representatives of the study team;
- The University of Pennsylvania Institutional Review Boards (the committees charged with overseeing research on human subjects) and University of Pennsylvania Office of Regulatory Affairs
- The University of Pennsylvania Office of Clinical Research (the office which monitors research studies)
- Authorized members of the University of Pennsylvania and 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.).

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

As part of the study the Dr. Marina Cuchel, study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures to those listed below. Please note that your personal contact information (e.g. name, social security number, phone number, address, etc.) will not be provided to these groups.

Institutional Review Boards (IRBs), health authority inspectors, such as the US Food & Drug Administration

- Collaborators of the Principal Investigator who may be at other academic or commercial research laboratories.
- Government agencies that require reporting of reportable diseases
- The Department of Health and Human Service (DHHS)
- Other doctors and health care professionals who are involved in the study

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.

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 Investigator listed on page one of 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.

Consent

Dr. Marina Cuchel and/or the research team have given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

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 [Insert Institution Name] to use your personal health information collected about you for research purposes within our institution. You are also allowing the [Insert Institution Name] 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