UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT
INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title: **FLURPIRIDAZ F-18 PET/CT IMAGING FOR DETECTING PARATHYROID ADENOMAS IN PATIENTS WITH PRIMARY HYPERPARATHYROIDISM**

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Research Study Summary for Potential Subjects

You are being invited to participate in a research study. Your participation in this study is voluntary. You should only participate if you have a complete understanding of the study requirements and the risks associated with participation. 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 research study is being conducted to test the use of Flurpiridaz F-18(aka Flyrcado) PET/CT imaging to detect parathyroid adenomas. This study will investigate the ability of this PET/CT imaging study to detect parathyroid adenomas in comparison to other procedures, such as SPECT/CT sestamibi scan, that you receive as part of your regular care. If you agree to join the study, you will be asked to complete the following research procedures: A consent and screening visit, followed by an Flurpiridaz F-18 PET/CT scan. Your participation may last for up to 6 weeks, depending on scheduling restrictions. There is only one required in-person visit for this study, a screening visit and an imaging scan visit, both can be done on the same day.

The most common risks of participation are:
- **Flurpiridaz F-18 PET/CT scan**: Exposure to imaging radiation. 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 likely that you will see no effects at all. You will not be able to participate in this study if you are pregnant.

- IV placement: Bruising, bleeding, pain or infection at the site of injection.

Please note that there are other factors to consider before agreeing to participate such as additional 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 a history of primary hyperparathyroidism.

You are being invited to participate in a research study. 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 the study with your family, friends, or family doctor. Being in a research study is different from being a patient.

If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

The purpose of our research is to examine use of Flyrcado PET/CT imaging to detect parathyroid adenomas. PET/CT is an imaging technique that potentially offers better imaging quality and accuracy as well as improved convenience for patient as it takes less time to perform. This study will investigate the ability of this PET/CT imaging study to detect parathyroid adenomas in comparison to other procedures you receive as part of your regular care.

“Off-label” use is when an FDA approved drug is prescribed for a condition/use other than that for which the drug has been officially approved. Flyrcado has not been approved by the FDA for the use in detecting parathyroid adenomas.

The information we get from the Flyrcado PET/CT scan are experimental, and will not be used for any decisions regarding clinical care. The results of the scan will only be reported in your medical record as an abbreviated research report. If any of the scans reveal unexpected findings that could impact your medical treatment, you will be notified. Physician(s) will evaluate the significance of the findings and determine if any further action is required. Images from the Flurpiridaz F-18 PET/CT scan will be stored on our clinical imaging archive system of the University of Pennsylvania Health System.

How long will I be in the study and how many other people will be in the study?

We plan to include up to 20 participants in this study. The study will be done over approximately 1.5 years. Your participation in the active portion of the study will be dependent on scheduling of the PET/CT scan but will generally be less than 6 weeks.

What am I being asked to do?

Before any study related procedures are performed, you will be asked to read and sign this informed consent document. You will have an opportunity to ask questions before you sign the form. Your participation in this study will be based on meeting the criteria for undergoing the imaging scan.

Participation in this study will include the following study visits/procedures

- Pre-screening phone questionnaire
- Screening visit (in person) – review of medical history and current medications
- Flyrcado PET/CT visit
- After PET/CT study, your medical record will be reviewed to gather clinical and surgical information relevant to the project including post-op serum parathyroid hormone and calcium level 8-12 weeks after surgery. Imaging scans, such as SPECT/CT sestamibi results and scans will also be compared to the experimental PET/CT scan.

Screening visit for study eligibility

You will be eligible for this study if have a history of primary hyperparathyroidism, have no contra-indications to the imaging (claustrophobia, inability to lie still on the scanner), and meet the other requirements for the study. A study team member may have spoken with you in person or may call you by phone, contact you by email or by MyPennMedicine to go over the study and confirm your willingness to participate before we schedule research study procedures. We will collect the following information from you or your medical record.

- Demographic information, such as your date of birth, age, gender, race, and ethnicity. Menopausal status if you are female. A urine pregnancy test will be done if you are a woman who could get pregnant, the pregnancy test must be negative for you to continue with the study. Volunteers cannot be breast feeding during study participation as well.
- We will review your medical history with you and ask you about any previous diagnosis of medical conditions that may make you ineligible to continue with the study.
- We will review your available medical records and ask you some questions to be sure you do not have any reasons you would not be able to undergo a PET scan.
- We will discuss potential dates for scheduling the Flurpiridaz F-18 PET/CT scan visit. The scheduled date will be confirmed with you by the study staff.

- You will receive a phone call or email to confirm the date of your Flurpiridaz F-18 PET/CT scan.

Flurpiridaz F-18 PET/CT Scan Visit

In Nuclear Medicine scans, imaging is done with specialized cameras that can pick up the tiny radiation signals given off by a radiotracer and determine where the signals come from. In this way, we can form a picture of where the radiotracer goes after it is injected. If you agree to participate in this research, the scan we will perform is called a Positron Emission Tomography/Computed Tomography (PET/CT) scan, which uses a large doughnut shaped detection device to provide a map of where radiotracers go in the body and brain.

The imaging drug used for this study is called Flyrcado. This is an approved imaging drug for clinical use, however it is not FDA-approved for use in detecting parathyroid adenomas. **In this study, you will be requested to undergo one** Flurpiridaz F-18 **PET/CT scan performed at the University of Pennsylvania.** The Flurpiridaz F-18 PET/CT scan appointment will require approximately **2 1/2** hours of your time.

The following will occur on the day of the Flurpiridaz F-18 PET/CT scan.

- Your height and weight will be recorded before the start of the scan.
- A urine pregnancy test will be done if you are a woman who could get pregnant, the pregnancy test must be negative for you to continue with the PET scan study.
- An intravenous (IV) line (a small, flexible tube) will be placed in a vein in your arm or hand.
- You will receive an injection of Flyrcado and then undergo a PET/CT scan. This procedure involves lying face up on an imaging table while the scan is performed. You may request to pause the procedure and be taken off the table at any time. Nuclear medicine technologists and other study staff will be positioned outside the room to operate the equipment, but they will monitor the procedure continuously and remain available to assist you with any needs throughout the scan.

You will be asked to go to the bathroom if you need to and remove any metal objects before entering the PET/CT scanner. You will be injected with Flyrcado, using the IV that has been placed, once on the PET/CT scanner. During the scan, you will lie face up on the scanner table for about 60 minutes while the PET/CT machine collects imaging information.

Follow-up phone call

If you experience any uncomfortable symptoms, during the imaging time or any time (day or night) in the 24 hours following your PET/CT scan, you should contact the study doctor listed at the top of page 1 of this consent form. You will receive a follow-up phone call to ask about any changes to your health and to ensure that you did not experience

any unwanted side effects from the PET/CT scan. Generally, this call will occur on the day after the PET/CT scan. If this is a weekend or a holiday, then the follow up call may occur on the next business day. If you experience any symptoms that you think are related to the study, you may call the emergency number listed on the front of this consent document at any time. After your PET/CT study, your medical record will be reviewed to gather clinical and surgical information relevant to the project including post-op blood parathyroid hormone and calcium levels, which will be done as part of your standard clinical care.

What are the possible risks or discomforts?

In this part of the consent form, we tell you the side effects we expect from the tests in this study. There may be side effects we do not know about yet. If we learn about other side effects, we will tell you.

This research involves exposure to radiation that could affect a fetus or pregnant woman, or breast-feeding baby. Due to this risk, menopausal status, pregnancy and breast-feeding status will be queried prior to scheduling of the scan and on the day of the scan prior to injection. Women of childbearing potential will have a urine pregnancy test performed prior to injection on the day of the scan. This is a short-lived radiotracer that has very low risk of any risk to a fetus conceived more than a day after administration. No specific contraception is required, and incidental pregnancies will not be tracked or followed.

You may have side effects while on the study. Everyone taking part in this imaging study will be watched carefully for any side effects.

You should talk to your study doctor about any side effects that you believe are related to the imaging procedures. You should tell your study doctor about any new symptoms even if you are not sure what has caused them.

Flurpiridaz F-18 PET/CT scan

During the PET/CT scan sessions, you will be required to lie quietly and motionless while the camera collects imaging information. This may cause you to experience discomfort or musculoskeletal pain (such as back or neck pain). Some people do not like the small space (claustrophobia) and might feel confined or bothered by being in the PET/CT scan machine.

Radiation Risk

This research study involves exposure to radiation from Flurpiridaz F-18 PET/CT scan. Therefore, you will receive a radiation dose. These procedures are 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 likely that you will see no effects at all.

Flurpiridaz F-18 injection

There are no reported significant risks for Flurpiridaz F-18 injections, which have been studied in humans. There have been mild symptoms of pain, bruising or infection at the site of injection.

Flurpiridaz F-18 is a PET imaging agent approved for use in cardiac perfusion imaging. The potential side effects and adverse reactions reported in the drug package insert are primarily related to the fact that this agent is used as part of cardiac stress imaging. The side effects and adverse reactions include dyspnea, headache, angina pectoris, chest pain, fatigue, ST segment changes, flushing, nausea, abdominal pain, dizziness, arrhythmia, diarrhea, palpitations, back pain, cardiac conduction disturbance, rash, dysgeusia, cough, hypotension, anxiety, vomiting, pruritus, bronchospasm, dry mouth, blood pressure elevation, syncope, and wheezing. No cardiac stress imaging will be performed as part of this study. Previous safety analysis of Flyrcado have reported that all adverse reactions were unrelated to the drug itself, and were instead related to the cardiac stress imaging agent which is not part of this study.

There are no reported significant risks for Flurpiridaz F-18 injections, which have been studied in humans. There have been mild symptoms of pain, bruising or infection at the site of injection

All drugs have a potential risk of an allergic reaction, which if not treated promptly, could become life-threatening. Symptoms of an allergic reaction to the drug could include hives, shortness of breath or trouble breathing. In the unlikely event that you develop an allergic reaction, we will treat you immediately.

IV Line Placement Risks

An intravenous (IV) line will be placed into a vein in your arm or hand. Insertion of a needle may cause local pain or bruising, bleeding, a blood clot, or infection at the site of insertion. There is also the possibility of dizziness or fainting while the IV is being placed. Standard precautions will be taken to try to prevent any of this from happening.

Incidental Findings

It is possible that during the course of the research study, the research staff may notice an unexpected finding(s). Should this occur, the finding(s) will be considered by the appropriate personnel and the principal investigator on the study will inform you and your treating physician if necessary. These possible finding(s) may or may not be significant and may lead to anxiety about your condition and to further work-up by your physician. Your treating physician will decide if the unexpected findings are clinically significant and if follow up is needed.

Reproductive risks
You will not be able to participate in this study if you are pregnant or breast-feeding due to the risks to the fetus or child from radiation exposure. If you are a woman of child-bearing potential, you will be asked to have a urine test at the screening visit and before your Flurpiridaz F-18 PET/CT scan to test for pregnancy.

If you become pregnant during this study, please notify the study investigator or staff. You will be taken off the study and will not undergo any further study procedures. In the event of incidental pregnancy discovered prior to the research Flurpiridaz F-18 PET/CT scan you will not undergo the research scan and will be discontinued from the 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.

What other choices do I have if I do not participate?
Taking part in this study is voluntary. You do not have to join this study. There are standard clinical imaging options that you may receive as part of your medical care that do not require you to be part of this study. You are free to say yes or no. Refusal to take part will not result in any penalty to you and will not impact your clinical medical care. Talk to your doctor or family and friends about your choices before you decide if you will take part in this study.

Will I be paid for being in this study?
For the screening and the Flurpiridaz F-18 PET/CT scan visit, we may cover reasonable transportation costs (for example: cab fare, Lyft or Uber, SEPTA or parking costs) that you would otherwise have to pay in order to get to the scan appointment. Please ask the study staff about this when planning your visits. In addition to covering reasonable transportation costs, you will be paid $100 after completion of the Flurpiridaz F-18 PET/CT scan visit.

All payments will be made with Greenphire ClinCards. ClinCards are reloadable prepaid cards that may be used for in-store purchases (by selecting either the “credit” or “debit” option), online purchases, ATM, and cash advances at a bank. Funds added to the card should be available immediately, however, in some cases it may take 1 business day. If you lose your card, please ask the study staff about how to replace it. Please try to keep your card in a safe place as multiple replacements may result in a small fee. In order to

be registered into the Greenphire system, we will need to enter your social security number. Therefore, you will be asked to complete a W-9 form at this visit.

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.

Privacy and Security
Every attempt will be made to protect your privacy and secure your information when your contact information is used to register your ClinCard (reloadable debit/credit card that will be used for your study compensation) via the Greenphire website. Greenphire securely stores all clinical trial participant information. Greenphire does not sell, use or distribute clinical trial participant information for any purpose other than those needed to execute, service and maintain the ClinCard program (including ClinCard Direct Deposit and Travel Reimbursement methods). Greenphire protects the privacy of Electronic Protected Health Information (EPHI), disclosed or provided to them in compliance with the Security Standards for the Protection of EPHI.

While loss of confidentiality is possible, it is felt to be very unlikely due to the small number of professionals involved in the study with knowledge of this information. All clinicians and research staff involved are well trained in HIPAA practices.

Will I have to pay for anything?

There will be no charge to you for participating in this research study. You and/or your health insurance may be billed for the costs of any normal 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.

The cost of the Flurpiridaz F-18 PET/CT scan will be paid for by the study. The costs of the Flurpiridaz F-18 PET/CT scan procedure include IV placement, infusion of the tracer, scan costs, and the cost of the tracer. You or your insurance company will not be billed for any of these costs.

The cost for urine pregnancy test will be paid for by the study.

During the course of the study, there may be incidental findings (such as on the CT portion of the PET/CT exam) that will require additional testing. This information will be reported to you. The decision to follow up with additional testing will be made by the doctors involved in your medical care. If additional testing is performed, it will not be covered by the study or sponsoring institution.

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 the University of Pennsylvania to pay you or give you other compensation for the injury. If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. 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 in 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 the study doctor, 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 has 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. You may withdraw from the study by contacting the study doctor listed on the front page of this consent form.

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.

The confidentiality of your information will be protected in the following way during the study: All study records that contain information that could identify you will be stored on paper in a locked office and/or cabinet which is accessible by study team members only. Electronic storage of data will be either in the Penn Medicine electronic medical record or on secure network drives or databases that are managed by Penn IT and require password protected access that will be granted only to appropriate study staff and investigators.

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. At most, the web site will include a summary of the results. You can search this web site at any time.

What may happen to my information on this study?

Future Use of Data

Your identifiable information will be stored for future research purposes. Future researchers may receive information that could identify you. This can be done without again seeking your consent in the future, as permitted by law. The future use of your information only applies to the information collected on this study.

The following identifiers may be retained with your information: name, medical record number, date of birth.

Your information may be stored and used for future research purposes for an indefinite amount of time.

There are no plans to tell you about any of the specific research that will be done.

We may share your identifiable information with other researchers within Penn, or other research institutions, as well as pharmaceutical, device, or biotechnology companies.

We will not follow up with you to tell you about the specific research that will be done. We will not give you any results from these studies. It is possible that you may have chosen not to participate in these future research studies, had you been approached for participation.

There is a risk of breach of confidentiality (unintentional release of your information). We will do our best to make sure that this doesn't happen. However, we cannot guarantee total privacy. We will protect your confidentiality during storage and sharing by storing data in secure, locked files or protected electronic data storage that is only accessible to designated study team members and investigators.

You will likely not directly benefit from future research with your information. Research with your identifiable information may help others by improving our understanding of health and disease, improving healthcare and making safer or more effective medical therapies or imaging, and developing new scientific knowledge.

If you have questions about the storage of your information, or have changed your mind, you can contact Dr. Victor Babatunde at 215-220-9494. If you change your mind, we may not be able to withdraw data that have already been shared with other

researchers, but we can stop any future research use of your data after you have notified us that you have changed your mind.

Electronic Medical Record and Release of Study Related Information

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

If you have never received care within Penn Medicine and are participating in a University of Pennsylvania research study that uses Penn Medicine healthcare related services, an EMR will be created for you for the purpose of maintaining any information produced from your participation. The creation of this EMR is a requirement of 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). If you have been a patient at Penn Medicine in the past, information from your research participation will be added to your existing medical record.

What may be placed in the EMR?
Information related to your participation in the research (e.g., laboratory tests, notes from your physician, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by Penn Medicine.

Once placed in your EMR your information may be accessible to appropriate Penn Medicine workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by Penn Medicine to be appropriate to have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Penn Medicine also participates in automated information sharing through Health Information Exchanges (HIEs). HIEs securely share parts of your electronic health record, including research information, with other healthcare organizations involved in your care. This information is shared to improve the quality, safety and efficiency of your healthcare. To request that your health information not be shared through HIEs, please call 215-662-4484.

Will I, as a subject, have access to research related information within the EMR/?
The 21st Century Cures Act requires healthcare institutions to allow patients increased access to their electronic medical record. As part of your participation in this research, you will have access to research related information within your EMR through Penn Medicine's patient portal – called MyPennMedicine (MPM).

Some information specific to this clinical research study may be shared with you in a delayed manner, shared with you at the end of the study, or not shared with you. A research report that will not contain full scan results for the Flurpiridaz F-18 PET/CT will be shown in MPM.

Will I receive the results of research testing that may be relevant to my health?

Results that may be relevant to your healthcare may be released to you.

A short research report will be placed in your medical record for the PET/CT scan, however, this report will not contain detailed results, only a description of the injection and statement about any side effects or incidental findings noted.

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 or released during your involvement with this research study:

- Name
- Contact information such as: address, email address, and phone number
- Date of Birth
- Social Security Number (if we provide you reimbursement for travel or parking)
- Numbers that identify you such as your Medical Record Number, Health Plan ID numbers or other unique identifying numbers.
- Current and past medications or therapies
- Information from the tests and procedures described earlier in this document
- Previous procedure, diagnosis and treatment information from institutions other than Penn if it relates to your eligibility for this study.
- Emergency contact number, name and relationship

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 correctly
- to evaluate and manage research functions.

Where may my information be stored?

Information related to your participation in clinical research will be contained in a clinical trial management system (CTMS). A clinical trial management system (CTMS) is used to register your information as a participant in a study. This allows for your research data to be entered and stored for the purposes of study operational and financial applications and other activities required as part of the conduct of the research. Once placed in the CTMS your information may be accessible to other authorized personnel

at Penn Medicine that support research operations. Your information may be held in other research databases.

Who may use and share information about me?

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

- The investigator for the study and the study team
- Other authorized personnel at Penn Medicine and the University of Pennsylvania, including offices that support research operations
- Other research personnel with access to the databases for research and/or study coordination and as otherwise approved by the IRB

Who, outside of Penn Medicine, might receive my information?

Oversight organizations

- The U. S. Office of Human Research Protections (OHRP)

Once your personal health information is disclosed to others outside Penn 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 Penn Medicine procedures developed to protect your privacy.

How long may Penn Medicine use or disclose my personal health information?

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

However, Penn 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. Even if you withdraw permission, we may still use data that was collected prior to your withdrawal.

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 Penn 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 IRB at the number on page one of this form.

Please indicate what methods of communication you agree to or prefer (You may opt out of any of these options by NOT checking it)

____ Phone
____ Email
____ MyPennMedicine message
____ Text (Texting is not 100% secure. You are not required to agree to text messaging as a method of communication and you may opt out by **NOT** checking this option. If you agree to text messaging as a method of communication msg and data rates may apply.)

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