

**Advanced Molecular Imaging with *anti*-3-[18F] FACBC PET-CT to Improve the Selection and Outcomes of Prostate Cancer Patients Receiving Post-prostatectomy Radiotherapy**

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**NCT01666808**



**Emory University, Saint Joseph's Hospital, and Grady Health System  
Consent to be a Research Subject and HIPAA Authorization**

**Title:** Advanced Molecular Imaging with *anti-3-[18F] FACBC* PET-CT to Improve the Selection and Outcomes of Prostate Cancer Patients Receiving Post-prostatectomy Radiotherapy

**Principal Investigator:** Ashesh B. Jani, MD, MSEE

**Study Supporter:** National Institute of Health

**Introduction:**

You are being asked to take part in this study because you have had surgery to remove your prostate and your study doctor has recommended radiation therapy because your blood level of Prostate Specific Antigen (PSA) has been going up. (The PSA is a value that helps determine the aggressiveness of your prostate cancer.)

This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You may search this Web site at any time.

**Study Overview:**

The purpose of this study is to see if (1) using FACBC PET scan will be useful in helping your doctor plan your radiation treatments and (2) if, as a result of using the PET scan to plan your treatments, the outcome of radiation treatment will be improved.

FACBC is a radiotracer that is injected into the vein. After the substance is injected, scans called PET or Positron Emission Tomography are done. This is similar to having CAT scans or x-rays. In recent studies, FACBC has been shown to enter prostate cancer cells. FACBC has been approved by the FDA (Food and Drug Administration) for recurrent prostate cancer.

External beam radiation therapy is one of the standard treatments for men with prostate cancer who have a rising PSA after surgery. Different methods of radiation therapy are used, and it is not known which one is best. Most commonly, the area where the prostate was originally located before being removed (the prostate bed) is treated, without treating the lymph nodes in the pelvis. Prostate cancer can spread to the lymph nodes. There is some evidence in men who have not had surgery that radiotherapy to the pelvic lymph nodes may stop the cancer from spreading under some conditions. Since treating the pelvic lymph nodes can result in increased side effects, the benefit of this method of radiation therapy needs to be tested.

### **Procedures:**

You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor

- History and physical
- A CT (Computed Tomography) scan or MRI (Magnetic Resonance Imaging) of your abdomen and pelvis to determine if there is any evidence of cancer spread to the pelvic lymph nodes. A CT scan is a study using x-rays to look at one part of your body. An MRI is imaging using a strong magnetic field to look at one part of your body.
- A bone scan to determine if the cancer has spread to the bones.
- Review of the tissue from your prior surgery to remove your prostate to determine your Gleason score (a value that helps determine the aggressiveness of your prostate cancer).
- You will be asked to complete a form that asks questions on your urinary, bowel hormone, and sexual functions.

You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance (like drawing straws). A computer program will place you in one of the study groups. You will be randomized to **one** of two groups of treatment.

**If you are in group 1 (often called "Arm 1"):** You will receive radiation treatments to the prostate bed once daily, 5 days a week, Monday through Friday, the exact number will be decided by your study doctor. Each radiation treatment will take about 15-30 minutes.

**If you are in group 2 (often called "Arm 2"):**

You will have a FACBC PET scan that will be used to plan your radiation treatment.

**On the day of the scan,**

- You will be required to fast for 4hours before the scan.
- You will be given oral contrast to drink; this allows the abdominal organs to be better visible.

### **FACBC scan:**

The scans will be performed at the Emory Center for PET located in the Nuclear Medicine Department on the first floor of the Emory University Hospital or in the Winship Cancer Institute. The entire procedure will last about 2 hours, including set up and preparation time. Before the PET scan, you will be asked to not eat or drink for four hours. This will allow the FACBC to get in your blood system easier. You will meet with a technologist and doctor who are approved to work on this study, and who will be performing the procedures on you. An intravenous tube called a catheter (IV) will be inserted in a vein in your arm to be used later for injection of the FACBC. One hour

prior to scanning, you will drink 1 bottle (500 ml) of oral contrast over 1 hour to allow for better pictures of your abdomen and pelvic structures.

After placement of the IV, you will lay down on a mobile couch that will slide into the scanner. The scanner has the appearance of a large box containing a large round opening into which your body is placed. An initial “transmission” scans lasting about 1 minute in which the couch will move. This transmission scan is similar to a CAT scan and is used to correct for the effect of your body on the PET scan in order to produce better images. This transmission scan is done on the PET scanner and will look no different to you. You will then receive a slow injection through the IV tube of the FACBC. A set of PET scans (pictures) will be done over thirty minutes. The couch will move. When finished, the IV will be removed, and a urine specimen may be collected to test for how the body gets rid of the FACBC. You will be able to leave the PET Center after this time.

If you are medically eligible, depending on the results of your scan, you will receive radiation treatment to the prostate bed (and possibly, the pelvic lymph nodes) once daily, 5 days a week, Monday through Friday, the exact number of treatments and area to be treated will be decided by your study doctor. Each radiation treatment will take about 15-30 minutes. Also depending on the results of the FACBC scan, your doctor may recommend biopsy of suspicious areas or other therapies.

### **Follow-Up**

All patients will also be followed for a minimum of three (3) years with blood draws for PSA levels every six (6) months. We may follow your medical progress for up to five years total.

### **Risks**

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, researchers don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop radiation). In some cases, side effects can be serious, long lasting, or may never go away. In addition, some of the side effects may be life threatening and, in rare instances, may cause death.

The procedures described in this study may cause all, some, or none of the side effects listed here. These are common procedures that are considered relatively safe. Previously unknown side effects can also occur. If new side effects are reported, you will be told. It is also important that you give us accurate and complete information about your past medical history.

You may also find it uncomfortable to lie motionless during the approximately 30 minutes necessary to complete the scan. If you believe you cannot lie still for 30 minutes, you should not participate in this study.

Although the risk is small, it is possible to develop an allergic reaction to the FACBC. This can result in hives, rash, itching and difficulty breathing which may require emergency medical treatment. There have been no previous instances of allergic reaction.

**FACBC:** In previous studies with 100 patients, there were no problems reported. However it is important to report any unusual side effects that you are having such as itching, skin rashes, fever, chills, nausea, dizziness, and vomiting. Please also see the risks of radiation exposure below.

### **Radiation Exposure:**

This research study involves exposure to radiation from PET/CT scans, similar to those routinely used for medical purposes. This radiation dose is not necessary for your medical care and will occur only as a result of your participation in this study. The radiation dose that you will receive is estimated to be equal to or less than the annual radiation

exposure limit allowed for persons who are occupationally exposed to radiation (for example, x-ray technologist, and radiologist). The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. The risk for radiation-induced cancer from this study is minimal. The risk from radiation exposure of this magnitude is considered to be comparable to other everyday risks. There are currently no studies that show an increase in the risk of genetic mutation in the next generation of offspring.

**Risks and side effects related to the radiation therapy include those which are:**

Likely

- Tanning, redness, or darkening of skin in treatment area
- Rash, itching or peeling of skin
- Temporary hair loss in the treatment area
- Temporary fatigue
- Abdominal cramps
- Frequent bowel movements, sometime with urgency, or diarrhea
- Rectal cramps and irritation with pain on defecation
- Mild rectal bleeding that does not require treatment
- Bladder irritation with a stinging sensation
- Frequency or urgency of urination
- Small amounts of blood in the urine

Less Likely

- Urinary obstruction requiring the placement of a temporary urinary catheter and/or dilatation because of stricture (narrowing)
- Less ability to control urine (increased incontinence)
- Inability to achieve an erection (inability of the penis to become hard)
- Rectal bleeding that requires medication or laser treatment to stop

Rare but serious

- Injury to the bladder, urethra, bowel, or other tissues in the pelvis or abdomen requiring additional procedure or surgery, such as a colostomy (bag for stool)
- Intestinal obstruction requiring surgery

Reproductive risks

You should not father a baby nor donate sperm while on this study or during the first 3 months after cessation of therapy because the drugs and radiation in this study can affect an unborn baby. Check with your study doctor about what kind of birth control methods to use and how long to use them.

Intravenous Catheter: One tube will be placed in your vein (arm or hand.) It is called an intravenous catheter or IV. It is placed under sterile conditions by piercing the skin and underlying vein with a needle, over which is threaded the IV catheter and then the needle is withdrawn. When the catheter is placed or removed, the site of insertion may become sore or bruised. Rarely, bleeding or infection can occur at this site; however, this is highly unlikely. A small gauze pad or bandage is placed over the site after the IV catheter is removed. This is similar to what happens when one donates blood.

Vein Puncture

. Care will be taken to minimize these risks.

**New Findings**

We may learn new things during the study that you may need to know. We can also learn about things that might make you want to stop participating in the study. If so, you will be notified about any new information.

### **Benefits**

Taking part in this research study may not benefit you personally. The outcome for patients randomized to Group 2 may or may not be as good, or may be better, than patients in Group 1 receiving standard of care. We do know that the information from this study will help researchers learn more about how best to treat men who have a rising PSA after surgery to remove their prostate. This information could help future cancer patients

### **Compensation**

If you were enrolled in Arm 2 of the study, we will compensate you \$50.00 for travel expenses to Emory for the PET scan.

### **Alternatives**

Your other choices may include:

- Getting treatment or care for your cancer without being in a study; this could include the following options, either alone or in combination with each other:
  - External beam radiation therapy (typically, to the prostate bed)
  - External beam radiotherapy plus hormone therapy
  - Hormone therapy
- Taking part in another study
- Getting no treatment (With this choice, your tumor could continue to grow and your disease could spread )

Talk to your doctor about your choices before you decide if you will take part in this study.

### **Confidentiality**

Emory, Saint Joseph's Hospital, or Grady Health System will keep any research records that it creates private to the extent that this is required to do so by law. Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

### **Certificate of Confidentiality**

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

- Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

**Medical Record**

If you are or have been a patient at an Emory, Saint Joseph's Hospital, or Grady Health System, then you will have an Emory, Saint Joseph's Hospital, or Grady health System medical record. If you are not and have never been a patient at an Emory, Saint Joseph's Hospital, or Grady Health System facility then you do not have one. An Emory, Saint Joseph's Hospital, or Grady Health System medical record **will** be made for you if you have any services or procedures done by an Emory, Saint Joseph's Hospital, or Grady Health System provider or facility for this study.

Copies of the informed consent form and HIPAA authorization form that you sign will be placed in your Emory, Saint Joseph's Hospital, or Grady Health System medical record. Emory, Saint Joseph's Hospital, or Grady Health System may create study information that can help Emory, Saint Joseph's Hospital, or Grady Healthcare take care of you. For example, the results from study tests and procedures. These useful study results will be placed in your Emory, Saint Joseph's Hospital, or Grady Health System medical record. Anyone who has access to your medical record will be able to have access to all study information placed there. The confidentiality of the study information in your medical record will be protected by laws such as HIPAA Privacy Rule. On the other hand, some state and federal laws and rules may not protect the research information from disclosure.

Emory, Saint Joseph's Hospital, or Grady Health System do not control results from tests and procedures performed and/or analyzed at other places, so these result would not be placed in your Emory, Saint Joseph's Hospital, or Grady Health System medical record. They will not necessarily be available to Emory, Saint Joseph's Hospital, or Grady Health System to help take care of you. Emory, Saint Joseph's Hospital, or Grady Health System also do not have control over any other medical records that you may have with other healthcare providers and will not send any test or procedure results from the study to these providers. It is up to you to let these healthcare providers know that you are participating in a clinical trial.

Some tests and procedures that may be performed during this study by Emory, Saint Joseph's Hospital, or Grady Healthcare or other facilities or persons may not be looked at or read for any healthcare treatment or diagnostic purposes. These tests and procedures will only be looked at for research purposes and the results will not be reviewed to make decisions about your personal health or treatment except as explained earlier. The specific types of tests or procedures, if any, that fall within this category are listed below:

FACBC PET scan

A Data Safety Monitoring Board will be regularly meeting to monitor safety and other data related to this study. The Board members may receive confidential patient information, but they will not receive your name or other information that would allow them to identify you by name.

**Authorization to Use and Disclose Protected Health Information**

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for this study.

**PHI that will be Used/Disclosed:**

The PHI that we will use and/or disclose (share) for the research study includes

- Entire medical record.

- Results of exams, procedures and tests you have before and during the study including pathology results, laboratory results, and radiology results.
- FACBC PET scan results.

**Purposes for which your PHI will be Used/Disclosed:**

We will use and disclose your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study.

**Use and Disclosure of Your Information that is Required by Law:**

We will use and disclose your PHI when we are required to do so by law. This includes laws that require use to report child abuse or abuse of elder or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

**Authorization to Use PHI is Required to Participate:**

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the study, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

**People that will Use and/or Disclose Your PHI:**

The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory and Saint Joseph's Hospital may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- The National Institute of Health is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The research team and the Sponsor may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
  - Emory offices that are part of the Human Research Participant Protection Program and those that involved in study administration and billing. These include the Emory IRB, Western IRB, and other IRBs or privacy boards involved in this study; the Emory Research and Healthcare Compliance Offices; and the Emory Office for Clinical Research.
  - The Institutional Review Board at Saint Joseph's Hospital.
  - Grady Health System Research Oversight Committee.
  - Grady Health Systems or Saint Joseph's Hospital offices involved in the study administration and billing.



- Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration.
- Public health agencies.
- Research monitors and reviewer.
- Accreditation agencies.

**Expiration of Your Authorization**

This authorization will not expire because it is a research study.

**Revoking Your Authorization**

If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must write to:

Dr. Ashesh B. Jani  
Department of Radiation Oncology  
[REDACTED]  
Atlanta, GA 30322  
Tel: [REDACTED]  
Email: [REDACTED]

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in this study.

**Other Items You Should Know**

Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers or health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations and/or for other purposes besides this study.

**In case of Injury**

If you are injured by or become ill from being in the study, Emory, Saint Joseph's Hospital, or Grady Health System would help you get medical treatment. If you believe you have been injured by this research, you should contact Dr. Schuster. Phone: [REDACTED] or Dr. Ashesh B. Jani, [REDACTED] if you are being treated at the Emory Clinic. You should also let any health care provider who treats you know that you are in a research study. At Saint Joseph's Hospital contact Dr. Bruce Hershatter at [REDACTED]. At Grady Healthcare contact Dr. Joseph Shelton at [REDACTED].

If you get ill or injured as the direct result of being in this study, then, depending on what insurance you may have, the sponsor may pay for some or all of the costs for your medical treatment of the illness or injury if it:

- (a) is not a medical condition that you had before you started the study;
- (b) is not the result of the natural progress of your disease or condition;
- (c) is not caused by your failure to follow the study plan; and
- (d) is not proved to be directly caused by the negligence of an Emory employee. "Negligence" is the failure to follow a standard duty of care.

If your case meets all four of these requirements and you are uninsured or have Medicare or Medicaid, then the sponsor will pay all of the costs of your medical treatment for the illness or injury.

If your case meets all four of these requirements and you have private insurance, Emory or Grady Health System will look at the claims for these costs to see if they can be sent to your insurer for payment. Your insurer may be told that you are in a research study and given information about your treatment.

You will have to pay for any costs that the sponsor or your insurer does not pay. The sponsor will pay for any of the costs that are not paid by your insurance provider. The sponsor will not pay for costs like co-payments that your insurer says you have to pay.

Emory, Saint Joseph's Hospital, and Grady Health System have not set aside any money to pay you or to pay for your treatment if you get ill or injured from being in the study. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of Emory, Saint Joseph's Hospital, Grady Health System, or sponsor employee.

### **Costs**

You will not be charged for the FACBC PET scans, urinalysis, or blood work that is done before the FACBC and one week after. These costs will be paid for by the Sponsor.

You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will **not** pay for your regular medical care including any other care you receive related to your prostate problem, including the bone scan, CT or MRI scans, biopsies, radiation therapy, hormonal or other therapy.

If you have insurance, Emory or Grady Health System will submit claims to your insurance for items and services that the sponsor does not cover. Emory or Grady Health System will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory, Saint Joseph's Hospital, Grady Health System, and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory, Saint Joseph's Hospital, or Grady Health System will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

**Disclosure of Financial Interest**

Emory University and Dr. Goodman have a financial interest in the radiopharmaceutical FACBC being studied in this study because Emory has licensed the radiopharmaceutical FACBC to Nihon Medi-Physics Co. Emory University and Dr. Goodman receive research funding and are entitled to sales royalty from Nihon Medi-Physics, which is developing products related to the research. The terms of this arrangement have been reviewed and approved by Emory University in accordance with its conflict of interest policies.

**Voluntary Participation and Withdrawal**

Your participation is completely voluntary and you have the right to refuse to be in this study. You can stop at any time after giving your consent. This decision will not affect in any way your current or future medical care or any other benefits to which you are otherwise entitled.

The study doctors have the right to end your participation in this study without your consent for any of the following reasons:

- It would be dangerous for you to continue;
- you were to object to any future changes that may be made in the study plan;
- do not follow study procedures as directed by the study doctors;
- the sponsor decides to end the study.

**Contact Persons:**

If you have any questions about this study call the study coordinator. Call Dr. David Schuster or Dr. Ashesh Jani, if you have been harmed from being in this study. Call Dr. David Schuster if you have questions concerning the risk of radiation their telephone numbers are:

Dr. Ashesh B. Jani: [REDACTED]

Dr. David Schuster: [REDACTED]

Bridget Fielder, RN (Study Coordinator): [REDACTED]

Contact the Emory Institutional Review Board at [REDACTED] or [REDACTED]

- If you have questions about your rights as a research participant.
- If you have questions, concerns or complaints about the research. You may also let the IRB know about your experience as a research participant through our Research Participant Survey at <http://www.surveymonkey.com/s/6ZDMW75>

If you are a patient receiving care from the Grady Health System and you have a question about your rights, you may contact the Office of Research Administration at [REDACTED]

**Consent and Authorization**

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**TO BE FILLED OUT BY SUBJECT ONLY**

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

\_\_\_\_\_  
Name of Subject

\_\_\_\_\_  
Signature of Subject (18 or older and able to consent)      \_\_\_\_\_ Date      \_\_\_\_\_:\_\_\_\_\_ am / pm  
Time (please circle)

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**TO BE FILLED OUT BY STUDY TEAM ONLY**

\_\_\_\_\_  
Name of Person Conducting Informed Consent Discussion

\_\_\_\_\_  
Signature of Person Conducting Informed Consent Discussion      \_\_\_\_\_ Date      \_\_\_\_\_:\_\_\_\_\_ am / pm  
Time (please circle)

Study Coordinator (initial if applicable):

\_\_\_\_\_ *I attest that I participated in the informed consent discussion with the subject*  
\_\_\_\_\_ *I attest that I was present when the subject gave informed consent*

\_\_\_\_\_  
Signature of Study Coordinator      \_\_\_\_\_ Date