CONSENT TO PARTICIPATE IN A RESEARCH STUDY

LIST COMPLETE TITLE HERE

Study to be Conducted at: *List each facility name*
Address
City, State Zip

Sponsor Name: *List sponsor name here (if applicable)*

Principal Investigator: *List PI name and telephone number*

If your study includes children, use the following statement:

For legal guardians of minors, please note that any words referring to "you" (such as I, me, myself, you, your, yourself) also refer to "your child" throughout this consent form. Permission from you is required for your child to participate in this study.

INTRODUCTION
You are being asked to participate in a research study. The Institutional Review Board of the Greenville Hospital System has reviewed this study for the protection of the rights of human participants in research studies, in accordance with federal and state regulations. However, before you choose to be a research participant, it is important that you read the following information and ask as many questions as necessary to be sure that you understand what your participation will involve. Your signature on this consent form will acknowledge that you received all of the following information and explanations verbally and have been given an opportunity to discuss your questions and concerns with the principal investigator or a co-investigator.

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 can search this Web site at any time.

PURPOSE
You are being asked to participate in this study because …

The purpose of this study is …

Include the following:

- *Why the participant is being asked to be in the study;*
- *Background information on the condition being studied;*
- *Purpose(s) of the study;*
- *Information about whether or not the drug/device is approved by the Food and Drug Administration (FDA), and whether the drug/device is or isn't approved for this specific disease/condition, etc.;*
- *Clear identification of what is investigational about the study;*

- *Approximate number of participants involved nationally and/or internationally;*
- *Expected duration of the participant's participation; explain if study continues to collect information until the death of the participant.*

If you are a student and the study is part of a thesis, dissertation or class project, insert this text:

The investigator is conducting this study as part of the (thesis, class project) requirements of (university, school of nursing, etc.).

If your study involves specimen storage, insert the following text and include a 'Consent Form for Specimen Storage':

In addition to the treatment described in this consent form, the sponsor would like to store samples of your *[specify type of specimen to be stored]* for future scientific research studies. Information about storing your specimens will be addressed later in a separate consent form.

PROCEDURES

Include the following:

- *Clearly identify what is investigational about the study;*
- *Specific identification of any experimental procedures, drugs, devices, etc. and whether they are approved or not approved by the FDA;*
- *A complete description of the procedures to be followed;*
- *Specific identification of any experimental procedures, drugs, devices, etc. and whether they are approved/not approved by the FDA;*
- *How the participant will be placed into study groups;*
- *If study is double/triple-blinded, explain steps to break the code in an emergency;*
- *If the study involves collection of body fluids such as blood, peritoneal fluid, urine, etc., include the amount of fluid taken in teaspoons or tablespoons.*

POSSIBLE RISKS

Any treatment has possible side effects. The treatments and procedures used in this study may cause all, some or none of the side effects listed. There is always the risk of very uncommon or previously unknown side effects happening.

If your study involves the use of a drug or drugs, include the following:

It is possible that receiving the study drug with your regular medications, supplements, or some food (for example, grapefruit juice) may change how the study drug, your regular medications, or your regular supplements work. It is very important that you tell the study doctor about all medications or supplements you are taking during the study.

When describing complications related to cancer treatment (use if applicable):

These complications can sometimes lead to serious illness requiring hospitalization or lead to death.

Include the following:

- *Description of any known risks;*
- *Statement that particular treatment/device/procedure may involve risks that are unknown;*
- *List side effects related to each drug/device/procedure involved in the study;*

- *If your study involves the use of a medical device, include the following:*

  A problem or malfunction of the device which may increase your time in surgery under anesthesia.

- *If the study involves the possibility of an allergic reaction, include the following:*

  As with all medications, side effects may include allergic reactions. Allergic reactions may range from minor itching or rash to major reactions, which can lead to death.

- *Inserting an IV or Drawing Blood (use if needed):*

  Inserting a needle into a vein in the arm to receive fluids and study treatment or to collect blood samples may cause pain, redness, bleeding, bruising, fainting, a clot in the accessed vein and rarely, infection at the location where the needle is placed.

- *Chest Catheter Placement (use if needed):*

  The procedure may cause pain, redness, bleeding or bruising. It is unlikely, but possible that you could develop an infection, clotting of the catheter or collapse of the lung. If you have a chest catheter placed, you will sign a separate consent form, which will describe the procedure and side effects in detail.

- *Bone Marrow Aspirates and Biopsies (use if needed):*

  This procedure may cause some temporary pain or discomfort, redness, bleeding, bruising or possibly, infection at the location where the needle is placed.

- *Studies that involve questionnaires or daily diaries (use if needed):*

  Some of the questions in the *[specify questionnaires, diaries, etc.]* are of a personal nature and may be upsetting to some participants. Your doctor and nurse will be available to discuss these questions should you have a concern or problem. You do not have to answer any questions that you do not want to answer.

- *If the study utilizes drugs that may be harmful to reproductive cells, include:*

You should practice an adequate method of birth control while taking part in this study. If you think that you have become pregnant or caused a pregnancy during this study, please tell your doctor immediately.

*If this study is being done at Bon Secours St. Francis Health System, you **MUST** use the following wording, unless inappropriate:*

Whether you are a man or woman, you should practice an adequate method of birth control while taking part in this study.

- *If the study may be harmful to an unborn or nursing child, include (to the extent that the information is true):*

  This study may involve unknown risks to an unborn or nursing child. Women who are pregnant or nursing a child may not participate in this study. You must tell your doctor that, to the best of your knowledge, you are not now pregnant and that you do not intend to become pregnant during this study. You may be required to take a pregnancy test before you participate in this study.

- *If the study involves data collection (no medical treatment) and utilizes a consent form, include the following:*

  There are no known medical risks related to participation in this study. The greatest risk is the possible release of your personal health information. Your study records are considered confidential, but absolute confidentiality cannot be guaranteed. This study may result in presentations and publications, but steps will be taken to make sure you are not identified by name.

EXCLUSIONS
You cannot participate in this study if:

Include any exclusions of which the participant should be aware so he/she may exclude himself/herself from the study (for example, pregnancy, diabetes, or high blood pressure.)

Also, please tell your doctor if you are taking any drugs, or non-prescription medications or supplements, including vitamins or herbs, other than those being used in this research study because of the risk of possible and/or serious drug interactions. Also you should tell anyone who gives you medical care that you are participating in a research study.

POSSIBLE BENEFITS
It is not possible to know whether or not you may benefit from participating in this study. The treatment or procedures you receive may even be harmful. You understand that the information gained from this study may be used scientifically and may be helpful to others.

Include any benefits to the participant or others that may reasonably be expected.

ALTERNATIVE (OTHER) TREATMENTS

You can still receive evaluation and treatment for your condition if you do not participate in this study. Discuss any alternative treatments with your regular doctor and/or the study doctor before you decide to participate in the study. Your decision is entirely up to you. If you decide not to participate in the study, you will not be penalized or lose any benefits and your decision will not affect your relationship with your doctor or hospital.

Insert bulleted list describing appropriate alternative procedures or courses of treatment, if any, that might be of equal or greater benefit to the participant, or those which are not experimental.

COST TO YOU FOR PARTICIPATING IN THIS STUDY

Include one of the two following statements:

- *If sponsor is NOT paying for treatments/procedures/devices used in the study, include:*

  The costs of the drugs/devices/tests/procedures done as a part of this research study may or may not be covered by your health insurance company. Medicare should be considered a health insurance provider. Please ask about expected costs or insurance problems. These costs will be charged to you and your health insurance company in the usual manner. Please be sure to discuss these matters with your health insurance company before you sign this consent form. <u>You will be responsible for all charges not covered by your health insurance company.</u>

- *If the sponsor IS paying for treatment, include:*

  There will be no cost to you for participating in this study. The costs of any drugs, devices, tests and/or procedures used in this study will be paid for by the sponsor. The sponsor will not pay for your usual medical care for conditions that are not related to this study. Discuss this with the study doctor and study staff prior to making your decision about participation.

If there are some items the sponsor will pay for and some items the sponsor will not pay for, clearly identify all of these items.

PAYMENT FOR PARTICIPATION

To You:

Include one of the two following statements:

- You will not be paid to participate in this study.
- You will be paid to participate in this study. *Include a payment schedule, total amount, and any situations in which the subject would not be paid.*

To Investigators:

Include the following statement if the study is funded:

The investigators will be paid by the sponsor for time, effort, and oversight by the investigators and professional staff to perform procedures, tasks and accurately collect and submit data.

Include one of the following statements if the study is NOT funded:

- Neither the investigators nor professional staff will receive any special compensation above and beyond their regular salaries for time and effort to perform procedures, tasks, and accurately collect and submit data.
- The investigators will not be paid above their regular salaries for conducting this study.

To Institution:
The Greenville Hospital System *(or appropriate institution)* is being paid by the sponsor for staff and administrative costs associated with conducting this study.

COMPENSATION FOR INJURY AS A RESULT OF STUDY PARTICIPATION

Include the following statement:

> If you get hurt or sick because of treatment you have received in this study, emergency medical treatment is available but will be provided at the usual charge. The study sponsor may or may not pay for this treatment. You will be responsible for any charges not paid for by the sponsor.
>
> No financial compensation (payment) will be available to you from the study sponsor, the Greenville Hospital System or the investigators as part of this study. You or your insurance company will be charged for continuing medical care and/or hospitalization. You understand that you have not given up any of your legal rights by signing this consent form.

VOLUNTARY PARTICIPATION
Participation in this study is completely voluntary (your choice). You may refuse to participate or withdraw from the study at any time. If you refuse to participate or withdraw from the study, you will not be penalized or lose any benefits. Your decision will not affect your relationship with your doctor or hospital.

If applicable, include a statement that the study doctor and/or sponsor may withdraw the participant from the study at any time without the participant's permission, including a description of circumstances in which this may happen (e.g., if the participant did not follow study instructions).

If your participation in this study is stopped, your study doctor will discuss any tests or procedures that may be needed for your health and safety. You may refuse any or all of these recommended tests.

NEW INFORMATION
During this study, you will be told of any important new information that may affect your willingness to participate in this study.

If applicable, also insert the following language:

A Data Safety Monitoring Board will be reviewing the data from this research from time to time throughout the study. They will notify your doctor of any new information that you need to be told about.

AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study. These study records may be kept on a computer and will include all information collected during the research study, and any health information in your medical records that is related to the research study. Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. To evaluate the results of the study and for compliance with federal and state law, your health information may be examined and copied by the Food and Drug Administration (FDA), other governmental regulatory agencies, the Institutional Review Board of the Greenville Hospital System, the study sponsor and the sponsor's authorized representative(s). This study may result in scientific presentations and publications, but steps will be taken to make sure you are not identified.

Under federal privacy laws, your study records cannot be used or released for research purposes unless you agree. If you sign this consent form, you are agreeing to the use and release of your health information. If you do not agree to this use, you will not be able to participate in this study.

The right to use your health information for research purposes does not expire unless you withdraw your agreement. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Once your health information has been released, federal privacy laws may no longer protect it from further release and use.

If you have any questions about the privacy of your health information please ask your study doctor.

In lieu of 'HIPAA Authorization' language (above) when not applicable, i.e. employee studies not involving medical information/data, include the following:

CONFIDENTIALITY

Your study records are considered confidential (private), but absolute confidentiality cannot be guaranteed. Information may be kept on a computer. All records may be examined and copied by the Institutional Review Board of the Greenville Hospital System, and other regulatory agencies. This study may result in presentations and publications, but steps will be taken to make sure you are not identified by name.

CONTACT FOR QUESTIONS

For more information concerning this study and research-related risks or injuries, or to give comments or express concerns or complaints, you may contact the principal investigator, *put investigator's name and phone number here*.

You may also contact a representative of the Institutional Review Board of the Greenville Hospital System for information regarding your rights as a participant involved in a research study or to give comments or express concerns, complaints or offer input. You may obtain the name and number of this person by calling (864) 455-8997.

A survey about your experience with this informed consent process is located at the following website:

www.ghs.org/research

Participation in the survey is completely anonymous and voluntary and will not affect your relationship with your doctor or the Greenville Hospital System. If you would like to have a paper copy of this survey, please tell your study doctor.

CONSENT TO PARTICIPATE

My study doctor, _____, has explained the nature and purpose of this study to me. I have been given the time and place to read and review this consent form and I choose to participate in this study. I have been given the opportunity to ask questions about this study and my questions have been answered to my satisfaction. I have been given a copy of my study doctor's Notice of Privacy Practices. I agree that my health information may be used and disclosed (released) as described in this consent form. After I sign this consent form, I understand I will receive a copy of it for my own records. I do not give up any of my legal rights by signing this consent form.

_____
Printed Name of Participant

_____ _____ _____
Signature of Participant Date Time

_____ _____ _____
Signature of Witness Date Time

INVESTIGATOR STATEMENT

I have carefully explained to the participant the nature and purpose of this study. The participant signing this consent form has (1) been given the time and place to read and review this consent form; (2) been given an opportunity to ask questions regarding the nature, risks and benefits of participation in this research study; and (3) appears to understand the nature and purpose of the study and the demands required of participation. The participant has signed this consent form prior to having any study-related procedures performed.

_____ _____ _____
Signature of Investigator Date Time

Principal Investigator: *List PI name and telephone number*

Co-Investigators: *List all Co-Investigator names and telephone numbers*