

**Sponsor / Study Title:** Sponsor Name / “Protocol Title”

**Protocol Number:** Protocol Number

**Principal Investigator:** «PiFullName»  
(Study Doctor)

**Telephone:** «IcfPhoneNumber»

**Additional Contact(s):** «AdditionalStaffMemberContacts»  
(Study Staff)

**Address:** «PiLocations»

*[For studies involving radiation]*

If you participate in this study, you will be exposed to amounts of radiation above what you would normally receive in daily life. To be sure that you do not receive an unhealthy amount of radiation from your participation in this study, you should let your study doctor know if you have had, or are going to have, any other scans or x-rays as part of your medical or dental care. It is very important that you let your study doctor know if you already are participating in, or plan to participate in, any other research study that involves radiation exposure.

**WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?**

*[For research studies involving no greater than minimal risk of harm a statement is not required regarding whether any compensation and any medical treatment(s) are available if injury occurs.]*

*[For all industry sponsored research studies include the following paragraph]*

**[SPONSOR]** shall reimburse for reasonable and necessary medical expenses (the “Covered Expenses”) incurred by research subjects for medical care, including hospitalization, in the treatment of adverse reactions arising from study drugs, devices, intervention, procedures and tests following their administration or use in accordance with the protocol, which expenses were not caused by negligence or misconduct of any person in the employment of Wake Forest University Health Sciences or to your own failure to follow instructions. The **[SPONSOR]** is not responsible for expenses that are due to pre-existing medical conditions or underlying disease.

*[For NIH, Foundation and Departmentally Sponsored Studies greater than minimal risk include the following paragraph]*

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of

such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of \$25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of \$25,000 coverage for each claim and is limited to a total of \$250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at (336) 716-3467.

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should contact the study doctor at the telephone and address listed on the first page of this form.

## What About My Health Information?

*Provide information highlighted in yellow.*

In this research study, any new information we collect from you or information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: [List information that will be collected].

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health

Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries. [List other individuals, organizations, agencies, etc as applicable for the particular study.]

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB of record or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups, it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completed.

You can tell the study doctor that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to the study doctor's address listed on the first page of this form.

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people

who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

## SIGNATURES

Subject Name (Printed): \_\_\_\_\_

Subject Signature: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_ am pm

Person Obtaining Consent: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_ am pm

***The following should be included if you are recruiting subjects with diminished mental capacity or individuals who cannot otherwise provide informed consent:***

Legally Authorized Representative Name (Print): \_\_\_\_\_

The above named Legally Authorized Representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse etc.)

Relationship to the Subject: \_\_\_\_\_

Legal Representative Signature: \_\_\_\_\_ Date: \_\_\_\_\_ Time: \_\_\_\_\_ am pm