Header:

* Title of Protocol
* Font: Times New Roman size 12
* DO NOT USE ALL CAPS

Document:

* Font: Times New Roman size 12
* Aligned text to both left and right of margins
* *Italics used here indicate BMHCC IRB examples and optional language. The suggested language is NOT mandatory.*

Top of first page - centered: (Required)

* **INFORMED CONSENT FOR PARTICIPATION IN A RESEARCH STUDY**

Footer Top Left:

* Sponsor’s Version and Date
* BMHCC IRB ICF Template Version and Date
* Font: Times New Roman size 12

Footer Center: Pagination.

* Page # of ##

**INFORMED CONSENT FOR PARTICIPATION IN A RESEARCH STUDY**

**Title of Study:**

**Protocol No.:**

**Sponsor:**

**Investigator:**

**Participating Investigators:**

**Telephone:**

# INTRODUCTION

You are being asked to participate in a research study. Before agreeing to participate in this research study it is important that you read and understand the following explanation of the proposed procedures. This document describes the purpose, procedures, benefits, risks, discomforts and precautions of the study. It also describes the alternative treatments/procedures that are available to you and your rights to withdraw from the study at any time. No guarantees or assurances can be made as to the results of the study.

(Required):

The study site will be paid by the study sponsor (specify) for the use of the site’s facilities and for the work the research staff does for the research study.

# PURPOSE

(Required):

#  Include duration of the study, the expected time commitment for the subject, and expected number of subjects to be studied, and probability of random assignment, if applicable.

# PROCEDURES

(Required):

# List all routine care tests and/or research (experimental) related tests/procedures and describe their purpose. Be sure to identify which procedures are experimental. In simple language, using a bullet point format with headers or table, explain the following:

* The tests and procedures that will be done (including medical record abstraction)
* Which procedures/drugs are standard of care and which are for research purposes only
* If research procedures will occur at a standard of care visit, indicate how much additional time will be required to complete the research procedures
* The method of assignment (randomization, etc.)
* The chances of being assigned to various arms
* Whether a placebo will be involved
* The amount of blood to be drawn for research purposes at each visit (in teaspoons/tablespoons)
* Estimate the time required of the subject for each visit

# POSSIBLE RISKS

(Required):

In simple language and in simple bullet format, explain the possible risks and discomforts, including:

* Potential risks of investigational agents, devices, procedures, and treatments, as well as known risks of comparative agents, devices, procedures, and treatments used in the study;
* If applicable, psychological, social, or economic risks; and
* Only include the risks associated with procedures and/or treatments being performed solely because the subject is participating in this research study. Risks of routine procedures that would normally be performed even if the subject were not participating in this research study should not be included in the consent form. However, if randomizing to a standard of care treatment when other standard of care treatments/alternatives exist, the risks of the standard of care treatment should be included because the patient may not incur these risks outside of the study.

*(Optional):*

*Add the following statement only if the study involves an experimental treatment where some subjects are not randomized to the experimental drug/biologic/device:*

*“If you are not randomized to the experimental treatment, you will not be exposed to the risks listed above associated with the experimental drug, [insert name of study drug/biologic/device].*

*“If the study includes a placebo, list the potential side effects associated with the placebo immediately following the side effects of the study drugs.”*

(Required):

There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

The research procedures, etc. may have unforeseeable risks to the subject, or to an embryo, fetus or newborn, if the subject or the subject’s partner is or may become pregnant. You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

**ALTERNATIVE TREATMENTS & CHOICES**

(Required):

Include any alternative treatment(s) that may be available to the subject.

# POSSIBLE BENEFITS

(Required):

In simple language, indicate the possible benefit for both the subject and the ways in which the study has the potential to develop medical knowledge important to society. If there are no direct benefits to subjects associated with participation in the study, then this should be clearly stated.

# COSTS FOR PARTICIPATION

(Required):

State whether there are any costs to the subject/legally authorized representative for participating in the research study.

*For example:*

*The study may include tests and procedures that are conducted solely for the research study as well as tests and procedures that are conducted as part of your routine care (meaning you would receive this care whether or not you are in the research study). Some of the tests and procedures may be paid for by the study Sponsor while others are billable to you and your insurance company. Your insurance company may or may not agree with this determination. If your insurance company feels that the charges are for tests and procedures related to the research study they may deny payment, making you responsible for any charges that are not paid for by the study Sponsor. There is never any guarantee with any service that you will not incur some financial liability.*

*For example:*

*The Principal Investigator or his/her representative will discuss the tests and procedures with you. They will tell you what will be paid for by the Sponsor and what will be billed to you and your insurance. They will also discuss any additional tests and/or procedures that may be required due to changes in your condition during your study participation. You have the right to refuse to have any additional tests or procedures. If you feel that you have been billed in error, please contact the Principal Investigator or his/her representative whose name and telephone number is included on this consent form.*

*For example:*

*A summary (insert a narrative or table‐formatted description with headings of “Covered by the Study” and “Payable by You or Your Insurance”) of the routine and investigational study‐related procedures is included below together with an indication of those items that will, or may, be the patient’s financial responsibility.*

# COMPENSATION FOR INJURY

(Required):

Compensation statement outlining what will be paid and by whom. If compensation for injury language does not apply to the research, delete this entire section.

If you think you have been hurt by taking part in this study, tell the study doctor immediately by calling << insert PI’s name and contact number >>or<< 24 hour number when applicable.

Baptist Memorial Hospital (specify BMH facility i.e., Desoto, Collierville, Memphis, etc.) and/or [insert clinic name] will provide medical and ancillary services ordered by your physician at the established charges for those services and either Sponsor, you, or your insurance will be billed.

*Neither [insert clinic name] nor Baptist Memorial Hospital (specify BMH facility i.e., Desoto, Collierville, Memphis, etc.) has funds for patient compensation of any kind. Therefore, they cannot provide payment for study injuries.*

*(As Applicable):*

*The sponsor will pay for the treatment if your injury is the direct result of your participation in the study, use of the study drug/device and properly-performed research procedures. If the sponsor pays for the treatment of your injury, you will be obligated to provide them with some personal information such as your social security number as they must report the payment to CMS.*

You do not waive any legal rights by signing this consent form.

# COMPENSATION FOR PARTICIPATION

(Required):

If compensation is not provided to subjects associated with participation in the study, this should be stated.

*For example:*

*You will not be paid for participating in this research.*

(Required):

If payment will be made, explain the following:

* the amount of the payment, or of each payment if there is more than one
* the total possible payment
* in what form payments will be made (cash, check, type of gift card)
* when payments will be made
* whether payments will be made to the participants OR their legally authorized representatives

# if the amount of payment exceeds $600 in a tax year, the subject will be responsible for paying any state, federal, social security or other taxes. No taxes are withheld from this payment. This payment to you may be considered taxable income by the Internal Revenue Service (IRS) and you may be issued a 1099-Misc Form. This form is sent to the IRS to report any money that is paid to you. To receive payment, you must agree to complete a W-9 form which requires you to provide an address and social security number to the accounting department. Waiver of payment is acceptable if you choose not to complete the W-9 form but continue to participate in the study. You are welcome to decline the payment if you would like.

# CONFIDENTIALITY (HIPAA)

# (Required):

**What is the HIPAA Privacy Rule?**

The “Privacy Rule” is a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that protects certain health information. It was issued by the government to make sure that your medical and health information is protected and not shared with others without your permission. Participants in research studies may be protected by this regulation. Most participants in research studies will need to sign an informed consent form which includes an Authorization for the use and release of certain health information.

**What is “Protected Health Information” (PHI)**

Protected health information (PHI) is information about you and your health. Examples of protected health information (that may be collected and used in this study) are:

* Personal information such as your name, initials, social security number, date of birth, age, address, race and sex
* Information that describes your disease and/or condition
* History and treatment of your disease and/or condition
* Past and current medical history
* Other medical conditions that may affect your treatment
* Medications that you may be taking or have taken in the past
* Medical data like laboratory test results, tumor measurements, CT scans, MRIs, X-rays, EKGs, and pathology results
* Information about side affects you may have and how they were treated
* Follow-up information about your general health and disease after your treatment.

**Why this information is being used and/or given to others?**

Information is collected for this study:

* To do the research
* To study the results of the research, and
* To see if the research was done right.

**Research records/specimens**

(Required):

Explain how paper research records will be maintained.

*For example, “All your paper research records will be stored in locked file cabinets and will be accessible only to research personnel and the specified entities listed in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).”*

(Required):

Explain how electronic research records will be maintained.

*For example, “All your electronic research records will be computer password protected and accessible only to research personnel and the specified entities listed in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).”*

***[OR]***

*“All your electronic research records will be kept on an encrypted computer where your information is replaced with a code and password only known to the research personnel, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).”*

**Medical Records**

(Required):

[*Explain if documentation of the participation of the subject in the research study, such as a copy of the consent form or other notation, will be placed in the subject’s medical record. For example:*]

Information about your participation in this study or the results of procedures performed in this study will be placed in your medical record; as such, this information could be made available to your employer or insurer.

[***OR***]

Information about your participation in this study or the results of procedures performed in this study will not be placed in your medical record.

**Presentations/Publications**

(Required):

Explain whether or not individual subjects will be identified in any presentations or publications based on the research.

*For example, “While individual details about your case might be provided in publications or presentations about this research, they will not be discussed in a way that would allow you to be individually identified as a participant.”*

**Authorization to Use and Disclose Information for Research Purposes**

 (Required):

Most studies require authorization to use your private health information, signing this consent form provides that authorization for this study. This section of the consent form is intended to inform you about how your health information will be used or disclosed in the research study. Your information will only be used in accordance with this informed consent form and as required or allowed by law. Please read carefully before signing.

Your health information related to this research study, may be used or disclosed in connection with this research study, including, but not limited to, (List or describe the protected health (medical) information that will be collected in this study.  The information should be limited to the least amount of information needed to accomplish the purpose of the research (i.e., information relating to a particular medical condition, specific blood tests, specific physical examination measures, specific x-rays or MRI imaging information, including any reports such as radiology or pathology reports.)

Describe how the individual’s health information will generally be used in the study, including any publication. If this is a clinical trial, also explain that the information in some form will be submitted to the sponsor and the FDA.

**Entities with Potential Access to your PHI**

 (Required):

The following parties are authorized to use and/or disclose your health information in connection with this research study:

* The principal investigator
* The research team
* Baptist Compliance Office
* Baptist Institutional Review Board - The Baptist IRB is a committee established to review and approve research involving human subjects. The purpose of the IRB is to ensure that all human subject research be conducted in accordance with all federal, institutional, and ethical guidelines. The mission of the IRB is to protect the rights and welfare of human research participants. The Baptist IRB may review your PHI as part of its responsibility to protect the rights and welfare of research subjects.

 (List every other class of persons or organization affiliated with Baptist who might need to use and/or disclose the participant's information in connection with this research study.)

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

* The sponsor or an agent for the sponsor, funding agency or collaborators who may receive information.
* Department of Health and Human Services
* The Office for Human Research Protection
* Food and Drug Administration (if applicable)
* Federal and other regulatory agencies as required

List every other class of persons or organization not affiliated with Baptist -- e.g., a sponsor, data safety monitoring board, collaborators at other institutions, outside data analysts, the National Institutes of Health, etc. -- to whom the participant's information might be disclosed.

Because of the need to release information to these parties, absolute confidentiality cannot be guaranteed. Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity will not be disclosed except as authorized by you or as required by law. However, there is always some risk that even de-identified information might be re-identified.

If this research study falls under the jurisdiction of the FDA, include the following:

The purpose of this research study is to obtain data or information on the safety and effectiveness of (insert name of drug, device, etc.); the results will be provided to thesponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

**Confidentiality**

*1.* Describe the way confidentiality of records identifying the research subject will be maintained. Use the following, if appropriate: Your part in this research study is confidential. None of the information will identify you by name. All records will *[describe how records are to be maintained].*

2. All records will be [*describe how they are to be maintained*].

*3.* Alternatively, if the study is anonymous, then this should be stated here. Indicate to the subject how anonymity will be preserved.

**Cancellation of Authorization**

(Required):

Your authorization for the use and/or disclosure of your health information will end on (date) or when the research project ends, whichever is earlier. List a specific date on which the authorization will expire, e.g., “will end on December 31, 2045”). If you are uncertain, choose a date that provides plenty of time for your work to be completed.

If you terminate this authorization, continued use of your PHI already obtained before the termination is permitted and its use is necessary in completing the research. However, PHI collected after your termination of this authorization may not be used in this study. If you refuse to sign this authorization, you will not be able to participate in this research study. If you terminate this authorization, then you will be withdrawn from the study. You may terminate this authorization in writing at any time by contacting the principal investigator or study staff by sending a letter to this address:

* Trial Site Name
* Address
* City/State/Zip

I understand that the medical provider may not make my treatment conditional on whether or not I sign the authorization.

I understand that this authorization is voluntary and that I may refuse to sign this authorization. I understand that my refusal to sign this authorization does not affect payment for services, my ability to obtain treatment, or my eligibility for benefits or enrollment.

If the research involves treatment include:

To maintain the integrity of this research study, your right to access your health information that is created or obtained by your health care providers as part of this research study may be suspended until the study has been completed.  Your right to access your health information related to the research study will be reinstated upon completion of the research study.  If you authorize release of your medical record to a third party after the conclusion of the research study, please be aware that your medical record will likely contain information about your participation in the research study.

# CONTACT FOR QUESTIONS

(Required):

If you would like to speak with the investigator to discuss any questions, concerns, problems, or injuries, please call [fill in name and contact info]

(Required):

If you would like to speak to a person who is not affiliated with this research study to discuss problems, concerns or questions, or to obtain information or offer input please call Rev. Anthony Burdick, Director of Pastoral Care, Baptist Memorial Health Care Corporation at 901-226-5025.

#  VOLUNTARY PARTICIPATION

(Required):

Participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which you would otherwise entitled, and you may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

(Required):

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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.

**STUDY WITHDRAWAL**

(Required):

If you choose to withdraw you should talk to your doctor about the potential risks and discuss the best way to withdraw from the study. Once you withdraw you will not be able to continue in the study. No new data will be added to the database once you withdraw, but all data collected prior to withdrawal may still be used as part of the study.

(Required):

 Include specific procedures for withdrawal and circumstances under which a subject may be terminated from the study.

**NEW FINDINGS:**

(Required):

Any new findings that may impact your decision to continue participation will be [fill in method].

THIS SPACE HAS BEEN

INTENTIONALLY LEFT BLANK

# CONSENT TO PARTICIPATE

The research study, procedures, risks and benefits have been explained to me. I have read and understand all of the above, been given the opportunity to ask questions, and my questions have been answered to my satisfaction. I voluntarily agree to participate in this research study. I will be given a copy of this signed and dated consent form for my own records. I do not give up any of my legal rights by signing this consent form.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Adult Participant (printed)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Adult Participant Date/Time

Or

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 \*Legally Authorized Representative (printed)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Signature of the Legally Authorized Representative Date/Time

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship to patient

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Person Obtaining Consent (printed)

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent Date/Time

\*If authorization is to be obtained from a legally authorized representative (e.g., parent(s), legal guardian or conservator) a description of his/her authority to act for the participant is also required.