**Informed Consent
To Participate in a Research Study**

|  |
| --- |
| **Title** |
| [Study Title] |
|  |
| **Principal Investigator** | **Phone**  |
| [PI Name] | [(000) 000-0000] |
|  |  |
| **Sponsor** | **Protocol No. and Version** |
| [Sponsor Name] | [Protocol No., Protocol Version] |
|  |
| **MHS Project No.** |
| [MHS Project No.] |
|  |

Compensation and Reimbursement

|  |
| --- |
| * Indicate if subject compensation and/or reimbursement is included as participation in the study by including information and language from the appropriate option below. Describe compensation or reimbursement with **one** of the following (Option 1 or 2):
 |

**Option 1** — If no subject compensation or reimbursement is provided, use the following language: You will not be paid for taking part in this study.

**Option 2** — If Subject compensation or reimbursement is provided, specify payment information and include the language below. Payment information should include the amount of per-visit compensation/reimbursement provided, the total amount possible, when payments will occur, and what form of payment will be received (check, cash, or gift card).

If you are paid over $600 in a calendar year, MemorialCare will request a W9 from you and will issue you a 1099 to meet IRS regulations.

We will ask you to provide your name, mailing address, and social security number so we can pay you.

Additional content if applicable (regardless of which option is used): If the study involves the collection of specimens, include the following language: This study includes providing your specimens to the researcher, sponsor, and potentially other parties. If new commercial products are developed from research using your specimens there are no plans for you to share in profits.

Costs and Research Related Injuries

What are the costs of taking part in this study?

|  |
| --- |
| * Include (only) one of the following cost language options below depending upon study type. If you have questions about what kind of study you have, contact MemorialCare Research Finance Office at (657) 241-3740.
 |

**Option 1** No cost for participating, e.g., data or survey research, the following language is used: There is no cost to you for participating in this study.

**Option 2**

You and/or your insurance will not have to pay for the tests, treatments, and procedures that are being done only for research. As part of this study, you or your insurance will be billed for tests, treatments and procedures that *[insert institution name]* considers to be routine clinical care of your condition. This may include:

* The costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety and prevent and treat side effects.
* *[Include only if applicable to the study]*The costs of getting the *[insert name of drug/device/biologic]* ready and giving it to you.
* Your insurance co-pays and deductibles.

Not all insurance plans cover the costs associated with being in a study. You may be responsible for out-of-pocket expenses. Taking part in this study may mean that you will have additional visits to the clinic or hospital and additional tests or procedures than if you were receiving the standard of care to treat your condition.

If you have questions about the cost, ask your study team. You can also call the Research Finance Office at (657) 241-3740 to connect you with the right person in Patient Financial Services. participating in this study.

*[If study drug/device is being provided at no cost, include:]*

The study drug/device, [*insert drug/device name*], will be provided to you at no cost.

What Should I Do If I Have a Research-Related Injury?

|  |
| --- |
| * Always include the first paragraph
* Select (only) one of the appropriate injury language sections below depending on study type and funding source.
 |

If you think you have been hurt by taking part in this study, tell the study doctor immediately. If you require treatment because you were injured from participating in this study, treatment will be provided. You should tell the treating doctor that you are participating in a clinical trial and give them your study doctor’s contact information. Your study doctor can be reached at the telephone number and address listed on the first page of this form.

*Option 1 (no compensation for Injury available):* If you believe the project is minimal risk, OR there is no compensation for injury offered (e.g. MemorialCare, federal grant, or other private foundation funding), include the following statement:

The study sponsor, [sponsor/funding agency name], and your study doctor will not offer to pay for any medical diagnosis or treatment for illness or injury caused by the study. You and your insurance company will have to pay for the cost of this treatment. However, by signing this form you have not given up any of your legal rights.

Option 2 (industry sponsored):If the project is industry sponsored, the language below must be included verbatim. NOTE — If industry sponsor does not agree to this language and other language is mutually agreed upon with approval from Legal and the Vice President of Research Administration.

The sponsor will pay for the diagnosis and treatment of your illness or injury if it is the direct result of your participation in the study. If the sponsor pays for the treatment of your illness or injury, you may be required to provide them with some personal information such as your social security number as they may need to report the payment to Medicare or your insurance company. No other compensation is available. However, by signing this form you have not given up any of your legal rights.

Confidentiality

Overall results of this study may be published. MemorialCare does not control if study results are published.

Study Consent

*Informed Consent template signature section will be accepted however the following standard section must be included.*

**Certificate of Investigator/Investigator Designee\* Obtaining Consent**

\*Designee must be IRB approved to perform informed consent

I have provided an explanation of the above research study and encouraged the subject to ask questions and request additional information regarding the study, its risks and complications and possible alternatives. I have answered all questions, and will answer any future questions, to the best of my ability. A copy of this signed consent form will be given to the subject.

Signature of Person Printed Name of Person Date Obtaining Consent Obtaining Consent