**Thomas Jefferson University**

**Consent Form for a Research Study**

**Official Study Title**:

**Study Title for Participants: [Lay Title]**

**Sponsor/Funding Agency:**

**Principal Investigator (PI):**

**PI Department:**

**Site Investigator: [include if multi-site study, see instruction manual for definitions]**

**Telephone: [Contact information for both PI and site investigator, as applicable]**

**Address: [Contact information for both PI and site investigator, as applicable]**

**What Is the Key Information You Need to Know About This Study?**

*The information in this section will give you an overview of key information to help you decide whether or not to participate in this study. There is a more complete description of this study in the pages that follow. Please read this description carefully and be sure to ask any questions you have.*

* You are invited to participate in a study. The purpose of this study is **[include a brief explanation of why the study is being done]**. You are invited to be in this study because **[briefly explain why the person is being asked to participate in the study, (e.g. have been diagnosed with a certain condition or meeting certain eligibility requirements)]**.
* Your participation in this study will involve **[number]** visits and will last about **[expected duration in hours, days, months, years]**. We expect about **[number]** people at Jefferson and about **[number]** people **[around the U.S./worldwide]** will join in this study.
* Participation in this study will involve **[provide a brief description of any procedures, drugs, and/or devices that the participant will experience as a part of this study]**.
* Most studies involve some risk. Risks of this study are **[significant/minimal]**. These risks are described in detail later in this document.
* You **[may/may not/will not]** personally benefit from participation in this study. **[If potential benefit, briefly describe.]** Other people may be helped by what is learned.
* You should carefully consider the reasons you may or may not want to participate in this study. This would include:
	+ the length and frequency of study visits and overall duration of the study
	+ your ability to follow all study requirements, like completing questionnaires or eating only certain types of food
	+ your experience of potential physical and non-physical risks
	+ your comfort and understanding of study procedures
	+ if this study involves a placebo, the possibility that you may or may not receive active study drug. **[remove this bullet point if not applicable]**
* Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. These may include **[briefly describe any alternatives the participant will have aside from participating in this study]**. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

**How Is This Study Different From Standard Medical Care?**

**[SEE INSTRUCTIONS FOR ADDITIONAL INFORMATION THAT MUST BE INCLUDED HERE.]**

**Will You Receive Payment for Participating in This Study?**

**[Describe the payment schedule and/or reimbursement OR include the following sentence:]**

You will not be paid for taking part in this study. If this study or the information or specimens you provide result in commercial profit, you will not receive any money from that profit.

**What Happens if You Leave the Study Early?**

There are a number of reasons you may decide or be asked to stop the study early (example: medical issues). You may also have to stop the study early even if you do not want to. You and the study personnel will discuss the reason if this becomes necessary. If you do leave the study early, you may be asked to complete some of the procedures described in this form. **[Describe any other actions/procedures that will occur if the participant has to leave the study early.]**

**What Happens if New Information Becomes Available?**

New information may come out during this study. You will be given any new information that could change your decision to take part. You may ask to see the information collected about you, but not until the entire study is complete. You **[will/will not]** be given any study results that could affect you. **[Modify this as necessary and include under what conditions the participant would/would not be given the results. An example of this would be a separate condition that may be detected while doing the test for this study. ]**

**What Can You Expect if You Decide to Take Part in This Study?**

**[SEE INSTRUCTIONS FOR ADDITIONAL INFORMATION THAT MUST BE INCLUDED HERE.]**

If you agree to be in this study, we will ask you to do the following things:

 **What Are the Risks or Discomforts of the Study?**

**[SEE INSTRUCTIONS FOR ADDITIONAL INFORMATION THAT MUST BE INCLUDED HERE.]**

Taking part in this study involves certain risks.

**[Include the following sentence if applicable:]** There may be different risks depending on what group you are assigned to.

**[Include the following sentence if applicable:]** There may also be risks that are not known at this time.

**[Include the following sentence if applicable:]** If we learn about new important side effects or risks, we will tell you.

**[Include the following sentence if applicable:]** If you have any medical issues during this study, call the appropriate number in the contacts section of this form.

**Are There Risks Related to Pregnancy or Breastfeeding?**

**[THIS SECTION IS ONLY INCLUDED WHEN APPLICABLE. SEE INSTRUCTION MANUAL FOR INFORMATION THAT MUST BE INCLUDED HERE.]**

**Will There Be Any Costs to You for Taking Part in This Study?**

**[SEE INSTRUCTIONS FOR ADDITIONAL INFORMATION THAT MUST BE INCLUDED HERE]**

You may have costs for participating in this study.

There is no plan to pay you for lost wages, lost time from work, personal discomfort, or for injuries or problems related to your underlying medical condition(s). You will be responsible for these costs. You will have to pay for basic expenses like any childcare, food, parking, or transportation related to study activities. You will be responsible to pay for your travel to and from the study site and other out-of-pocket expenses such as parking. If you are not sure about costs to you that may result from taking part in the study, you should talk to the study doctor or a member of the study team. If you receive a bill that you think is wrong, please contact the study personnel.

 **What Happens if You Become Ill or Are Injured While Taking Part in This Study?**

**[SEE INSTRUCTIONS FOR ADDITIONAL INFORMATION THAT MUST BE INCLUDED HERE.]**

To help avoid injury or illness, it is very important to follow all study directions.

* If you have an emergency, call 9-1-1 right away or go to the emergency room.

In the event of an injury or illness resulting from your participation in this study, you will be provided with medical care for that injury or illness within. However, Jefferson cannot ensure that the medical care and treatment will be provided without charge, and the costs of care may, ultimately be your responsibility.

**Is There Any Additional Financial Information You Should Know About This Study?**

**[Complete if applicable]** Jefferson is being paid by **[Insert Entity]** to conduct this study. **[Add any other financial disclosures for Jefferson or the investigators/study personnel.]**

**What Happens to the Information Collected About You During the Study?**

**[SEE INSTRUCTIONS FOR ADDITIONAL INFORMATION THAT MUST BE INSERTED HERE. INSERT OPTION 1 OR 2 FROM THE INSTRUCTION MANUAL HERE.]**

**Where Can You Find Additional Information About This Study?**

**[SEE INSTRUCTIONS FOR ADDITIONAL INFORMATION THAT MAY BE INCLUDED HERE]**

**Who Should You Contact About This Study?**

**If you are having a medical emergency, call 9-1-1 or go directly to an emergency room.**

**[Include the following sentence if applicable] You should let emergency personnel or providers know that you are taking part in this study.**

During the study, if you experience any medical problems, have a research-related injury, or have questions, concerns or complaints about the study, please contact the principal investigator at the telephone number listed on the first page of this consent document or other contact listed below.

**[Repeat phone numbers of PI and Site Investigator from above. Add additional contact information/phone numbers as would be helpful to the participant.]**

|  |  |  |
| --- | --- | --- |
| **For Questions About:** | **Person or Office** | **Contact Information** |
| The Study or Research-Related Injury | Principal Investigator: **[Name]**Site Investigator: **[Name]** | **[Phone Number]****[Phone Number]** |

An institutional review board (IRB) is an independent committee established to help protect the rights of study participants. If you need to contact someone other than the study personnel about a concern or your rights as a study participant, contact**:**

* By mail: TJU Office of Human Research

1020 Locust Street, Ste. M-34

Philadelphia, PA 19107

* or call: 215-503-0203
* Website/Email: https://research.jefferson.edu/clinical/personnel/human-research/contact.html

**Signatures**

Participant: By signing this form, you are agreeing that:

* You were given the opportunity to read this form.
* All of the information in this form was discussed with you by an investigator or other study personnel to your satisfaction.
* All your questions have been answered to your satisfaction.
* You were not pressured and you voluntarily agree to take part in this study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Participant |  | **Signature of Participant** |  | Date |

Person Obtaining/Assisting with Consent:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Person Obtaining/ Assisting with Consent |  | Signature of Person Obtaining/Assisting with Consent |  | Date |

Investigator:

**[SEE INSTRUCTIONS FOR THE APPROPRIATE INVESTIGATOR STATEMENT REGARDING MCARE PROCEDURES.]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Investigator |  | Signature of Investigator |  | Date |

Witness:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Witness |  | **Signature of Witness** |  | Date |

 *(A witness is required if the only language the participant speaks and understands is English, but the participant cannot read English, or if the participant is blind or cannot physically sign the consent form.)*

[ ]  **Copy of Signed and Dated Consent Form Offered to the Participant/Parent/Legally Authorized Representative (LAR)**

**[See Instruction Manual for alternative to the above statement.]**

**Surrogate Consent Form**

**[Include this surrogate consent form only if applicable.]**

**[For more complete information about surrogate consent, see OHR Policy IC 707. When this form is used to obtain surrogate consent, replace the signature page of the study consent form with this form. All forms used for consent must be IRB approved.]**

The participant may be capable of agreeing, or assenting, to be in the study in addition to obtaining consent from the surrogate. When this is the case, inform the participant about the study according to the participant’s level of understanding.

After surrogate consent, if the participant later becomes able to assent or consent and agrees to participate, they should sign this form (for assent) or the study consent form (for consent).

After surrogate consent, if the participant later becomes able to assent or consent and withdraws from the study, the study data obtained up to that point cannot be used unless the participant signs a written agreement (such as the HIPAA section of the consent form).

When a participant is initially able to consent but due to a medical condition may later lose the ability to make study decisions and provide continuing consent to participate, the participant should appoint a surrogate at the start of study participation. Document the surrogate in the participant’s study file.

1. **Name of Participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
2. Provide the reason the participant is unable to provide informed consent:
3. Although the participant is unable to provide informed consent, is the participant able to assent, or agree, to take part (check one)?

 [ ]  The participant is able to assent to take part.

[ ]  The participant is unable to provide assent for the reason stated above.

[ ]  The participant is unable to provide assent for the following reason:

1. **Printed Name of Surrogate: ­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
2. Check the appropriate box. The list is in order of authority per Jefferson policy.

[ ]  \*Legal Guardian

[ ]  \*Power of Attorney

[ ]  \*Health Care Representative

[ ]  Spouse

[ ]  Adult Child

[ ]  Parent (of an adult participant)

[ ]  Adult Sibling (Brother / Sister)

[ ]  Adult Grandchild

[ ]  Other Adult Relative

\*Documentation must be retained in the participant’s records.

**Signatures**

Surrogate and Participant if Assenting: By signing this form, you are agreeing that:

* You were given the opportunity to read the consent form.
* All of the information in the consent form was discussed with you by an investigator or other study personnel to your satisfaction.
* All your questions have been answered to your satisfaction.
* You were not pressured and you voluntarily agree to take part in this study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Participant |  | **Signature of Participant** |  | Date |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Surrogate |  | **Signature of Surrogate** |  | Date |

Person Obtaining/Assisting with Consent:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Person Obtaining/ Assisting with Consent |  | Signature of Person Obtaining/Assisting with Consent |  | Date |

Investigator:

**[SEE INSTRUCTIONS FOR THE APPROPRIATE INVESTIGATOR STATEMENT REGARDING MCARE PROCEDURES.]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Investigator |  | Signature of Investigator |  | Date |

Witness:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Witness |  | Signature of Witness |  | Date |

*(A witness is required if the only language the surrogate/participant speaks and understands is English, but the surrogate/participant cannot read English, or if the surrogate/participant is blind or is mentally capable but cannot physically sign the consent form.)*

[ ]  **Copy of Signed and Dated Consent Form Offered to the Surrogate/Participant**

**[See Instruction Manual for alternative to the above statement.]**

**Assent Form**

**[If the study does NOT involve assent, delete this entire form. This form should be used for studies that will involve assent (e.g., studies enrolling minors and/or individuals with impaired decision-making capacity at Jefferson). A separate assent form (i.e., sponsor-provided assent form) is also acceptable.]**

**Generally, the consent of a parent/guardian must accompany assent. [Remove the rest of this paragraph for studies that will involve adult assent but not child assent.] Participants under the age of 7 do not need to assent; however, the section below must still be completed. Participants age 7 – 17 should be given the opportunity to assent. In general, if the study has the possibility of direct benefit to the health of the child and is available only in the context of the study, the assent of the child is not required, but may still be requested.**

1. **Name of Participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
2. **Age of Participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
3. **Check one based on the participant’s age and level of understanding. The investigator or other qualified individual makes the determination of the participant’s level of understanding:**

[ ]  Due to the age/understanding of the participant, it was determined that effective assent could not be obtained. The participant’s name must still be printed below; however, signature and date does not need to be obtained.

[ ]  The participant is able to read some of the general information in the consent form. The consent information was discussed with the participant at the appropriate level of understanding.

[ ]  The participant was given the opportunity to read the general information in the consent form. The consent information was discussed with the participant at the appropriate level of understanding.

[ ]  The participant was given the opportunity to read the consent form. The consent information was discussed with the participant at the appropriate level of understanding.

You will take part in this study.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Name of Participant |  | **Signature of Participant** |  | Date |

The main consent form’s signature page must also be completed.