Please delete this sentence and all blue and red text, and highlighted items before submitting.

***Insert the below information, and update the Principal Investigator and Telephone information.***

**Thomas Jefferson University**

**Informed Consent Document for Human Subjects Research – OHR-8K (v.02/27/2019)**

**Principal Investigator**: **Telephone**:

Identify the corresponding sections of the study consent, as described below, and insert the necessary text.

1. If the consent template does not address research-related injuries, include the section below. If research-related injury is already addressed in the consent template, do not include the section.

# What happens in case of injury as a result of being in this study?

In the event of a research-related injury, necessary and available medical care (including hospitalization) will be provided. A research-related injury is a physical injury or illness that is directly caused by any procedure or treatment used in this study that is different from the treatment you would receive if not participating in a research study. If physical injury occurs due to any drug/substance or procedure properly given under the plan for this study, medical expenses for treating the injury will be billed to your insurance carrier. You should be aware that some costs may not be covered by insurance and may become your responsibility. There is no plan to provide compensation for loss of wages, lost time from work, personal discomfort, or for injuries or problems related to your underlying medical condition(s).

If you receive a bill related to a research-related injury that seems wrong, please discuss it with the study doctor or research coordinator.

1. Include the following section towards the end of the consent form. Phone numbers and websites are subject to change. If so, please update with most current information.

# Contact Information

*Please update per the highlighted sections and delete any investigator information/location(s) not conducting this trial per the below table*

|  |  |  |
| --- | --- | --- |
| **For Questions About:** | **Person or Office** | **Contact Information** |
| The Study or Research related Medical Issues | Jefferson –Center City Investigator: *Name*Jefferson Health – New Jersey Investigator: *Name*Jefferson Health – Northeast Investigator: *Name* | *Phone Number**Phone Number**Phone Number* |
| If you need to contact someone other than the study personnel about a concern or your rights as a research subject | Jefferson – Center City/Jefferson -New JerseyInstitutional Review Board (Ethics Committee) | 215-503-0203215-503-8966215-955-4239 |
| If you need to contact someone other than the study personnel about a concern or your rights as a research subject | Jefferson-NortheastRisk Management, Jefferson-NortheastPrimary Research Contact at Jefferson-Northeast | 215-612-5155215-612-5296 |

**Signatures**

*Make sure the finished signature page fits on one page.*

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

Your Name Your Signature Date

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

Name of Person Obtaining/ Signature of Person Obtaining/ Date

Assisting with Consent Assisting with Consent

Choose one of the following 3 options for the investigator’s signature (for studies being done in Pennsylvania) and delete the other 2 options.

Include for studies involving any Mcare procedures (See OHR policy IC 701).

The **physician investigator’s** signature certifies that s/he **personally** provided the study participant with a description of the study, study procedures, risks, benefits and alternatives to participation.

Include for studies that receive FULL IRB review but do not include any Mcare procedures (See OHR policy IC 701).

The **investigator’s** signature certifies that s/he **personally** provided the study participant with a description of the study, study procedures, risks, benefits and alternatives to participation.

Include for all other studies.

The investigator’s signature certifies that the study participant has been provided with a description of the study, study procedures, risks, benefits and alternatives to participation.

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

Name of Investigator Signature of Investigator Date

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

Name of Witness Signature of Witness Date

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