**Compensation for Research Related Injuries (Sponsor language must be consistent with CTA)**

Sponsor will reimburse Institution for reasonable and necessary medical expenses incurred by study subjects as a direct result of the treatment of an adverse reaction that is directly related to the study drug [device] or its administration in accordance with the Protocol, provided such expenses do not result from negligence or misconduct of any agent or employee of the Institution and the expense is not the result of the natural course of your disease or some other underlying condition. You will not lose any of your legal rights or release the Sponsor, the study doctor, the study staff, or study site from liability for mistakes or intentional misconduct by signing this consent document.

If you are experiencing an emergency, call 911. If you believe you have been harmed as a result of participating in this study, you should call [*PI’s name*] at [*insert telephone number*] as soon as possible.  The University of South Florida has not set aside money to pay for illness or injury that may result from your participation in research. The cost of such care will be billed to your insurance company or to you in the event you do not have medical insurance.  Before you agree to take part in this study, you may want to find out whether your insurance will cover injuries that result from taking part in research. You may be responsible for any deductible, co-insurance, or co-payments that result from such care. If you are injured, the University of South Florida has also not set aside money for lost wages, discomfort or disability you may experience as a result of a research related injury. You do not give up your legal rights by signing this form. In addition to contacting the study investigator, you should also contact the USF Institutional Review Board (IRB) at 813-974-5638 if you believe you have been injured as a result of taking part in this study.

# Privacy and Confidentiality

We will keep your study records private and confidential. Certain people may need to see your study records. Anyone who looks at your records must keep them confidential. These individuals include:

* The research team, including the Principal Investigator, study coordinator, research nurses, and all other research staff. [*Do not list the actual names of the Principal Investigator or staff as they may change over the course of the study*]
* Certain government and university people who need to know more about the study, and individuals who provide oversight to ensure that we are doing the study in the right way.
* Any agency of the federal, state, or local government that regulates this research. [*List Food and Drug Administration (FDA), Office for Human Research Protection (OHRP) as applicable*.]
* The USF Institutional Review Board (IRB) and [*Insert Independent IRB name here*] their related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance.
* The sponsors of this study and contract research organization [*If not applicable, please delete this item.*]

We may publish what we learn from this study. If we do, we will not include your name. We will not publish anything that would let people know who you are.

# Authorization to Use and Disclose Protected Health Information (HIPAA Language)

The federal privacy regulations of the Health Insurance Portability & Accountability Act (HIPAA) protect your identifiable health information. By signing this form, you are permitting the University of South Florida to use your health information for research purposes. You are also allowing us to share your health information with individuals or organizations other than USF who are also involved in the research and listed below.

In addition, the following groups of people may also be able to see your health information and may use that information to conduct this research *[delete bullets as applicable]*:

* The medical staff that takes care of you and those who are part of this research study;
* Each research site for this study including *[list all sites who will use and share PHI for this research study]*.
* Any laboratories, pharmacies, or others who are part of the approved plan for this study;
* All designated review committees such as [*Add all that apply: Data and Safety Monitoring Board; VA Research Services; etc.*];
* The USF Institutional Review Board (IRB) and [*Insert Independent IRB name here*] their related staff who have oversight responsibilities for this study, including staff in USF Research Integrity and Compliance and the USF Health Office of Clinical Research.
* Data Safety Monitoring Boards or others who monitor the data and safety of the study;
* There may be other people and/or organizations who may be given access to your personal health information, including [*List any other persons, classes of persons, and/or organizations. Do not list persons who are likely to change over the course of the study, instead list them by title or category only.*]

Anyone listed above may use consultants in this research study, and may share your information with them. If you have questions about who they are, you should ask the study team. Individuals who receive your health information for this research study may not be required by the HIPAA Privacy Rule to protect it and may share your information with others without your permission. They can only do so if permitted by law. If your information is shared, it may no longer be protected by the HIPAA Privacy Rule.

By signing this form, you are giving your permission to use and/or share your health information as described in this document. As part of this research, USF may collect, use, and share the following information *[Modify to match what data will be collected and used in your study]:*

* Your research record
* All of your past, current or future medical and other health records held by USF, other health care providers or any other site affiliated with this study as they relate to this research project. This may include, but is not limited to records related to HIV/AIDs, mental health, substance abuse, and/or genetic information.
* [*List any other needed information not included above. The descriptions should have enough detail that one (or an organization that must disclose information pursuant to this authorization) can understand what information may be used or disclosed.*]

You can refuse to sign this form.  If you do not sign this form you will not be able to take part in this research study. However, your care outside of this study and benefits will not change. Your authorization to use your health information will not expire unless you revoke (withdraw) it in writing. You can revoke this form at any time by sending a letter clearly stating that you wish to withdraw your authorization to use your health information in the research. If you revoke your permission:

* You will no longer be a participant in this research study;
* We will stop collecting new information about you;
* We will use the information collected prior to the revocation of your authorization. This information may already have been used or shared with others, or we may need it to complete and protect the validity of the research; and
* Staff may need to follow-up with you if there is a medical reason to do so.

To revoke this form, please write to:

Principal Investigator

For IRB Study # [*Insert your Pro IRB Study #*]

[*Insert complete mailing address*]

While we are conducting the research study, we cannot let you see or copy the research information we have about you. After the research is completed, you have a right to see the information about you, as allowed by USF policies.