Sponsor template consent forms may be sent to WIRB. The following is an example of a consent format. All language is sample language, except gray shaded, which is institution/WIRB required.

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:

PROTOCOL NO.:

WIRB® Protocol #

SPONSOR:

INVESTIGATOR:

SITE(S):

STUDY-RELATED PHONE NUMBER(S):

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

PURPOSE OF THE STUDY:

If applicable include: An investigational drug is one that is not approved by the U.S. Food and Drug Administration (FDA).

PROCEDURES

Please include information regarding tests and procedures (standard and experimental) that will be done at some or all of the study visits.

RISKS AND DISCOMFORTS

Include information regarding risks of study drug/device.

There may be side effects which are unknown at this time.

PREGNANCY LANGUAGE REQUIRED BY INSTITUTION

[OR OTHER PREGNANCY LANGUAGE SUPPLIED BY SPONSOR]

Drawing blood from your arm may cause pain, bruising, lightheadedness, and, on rare occasions, infection.

RISKS OF OTHER PROCEDURES IF NEEDED ESPECIALLY ANY INVASIVE PROCEDURE. FOR EXAMPLE endoscopy or tympanocentesis procedures.

IF A TREATMENT STUDY
Your [disease, condition, symptoms] may not get better or may become worse while you are in this study.

IF STUDY DRUG IS TAKEN HOME
Only you can take the study drug. It must be kept out of the reach of children and persons who may not be able to read or understand the label.

BENEFITS

Your [disease, condition, symptoms] may improve as a result of your participation in this study. However, there is no guarantee of this.

IF NOT A TREATMENT STUDY, "This is not a treatment study. You are not expected to receive any direct medical benefits from your participation in the study.

The information from this research study may lead to a better treatment in the future for people with [disease, condition, symptoms].

COSTS

Study drug will be provided by the sponsor. There are no charges for the study visits. *OR OTHER LISTING FURNISHED BY AUTHOR IF WILL BE BILLED FOR ANYTHING, NEED TO TELL THEM IF INSURANCE WILL BE BILLED, NEED TO TELL THEM; ALSO WHO WILL BE RESPONSIBLE IF INSURANCE DOESN'T PAY*

PAYMENT FOR PARTICIPATION

ONLY IF ARE PAYING, OR THE PROTOCOL SAYS MUST INFORM ARE NOT PAYING.

You will be paid $____ for each completed study visit. If you do not complete the study, you will be paid for the visits you have completed.

ALTERNATIVE TREATMENT

If you decide not to enter this study, there are other treatments available. These include *LIST OF MAJOR DRUGS AND/OR THERAPIES*. The study doctor will discuss these with you. You do not have to be in this study to be treated for *[disease, condition, symptoms*].

[IF NOT A TREATMENT STUDY - REMOVE "TREATMENT": FROM SECTION TITLE AND: This is not a treatment study. Your alternative is to not participate in this study.]

PRIVACY AND CONFIDENTIALITY

If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits

[board presenters to select additional from below as appropriate]

- Information obtained during this research about
  - HIV / AIDS
  - Hepatitis infection
  - Sexually transmitted diseases
  - Other reportable infectious diseases
  - Physical exams
  - Laboratory, x-ray, and other test results
  - Diaries and questionnaires
  - The diagnosis and treatment of a mental health condition
- Records about any study drug you received
- Records about the study device

The study doctor might give information about you and your health which might identify you to:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Governmental agencies to whom certain diseases (reportable diseases) must be reported
- The Western Institutional Review Board® (WIRB®)

[Add any institutional names above WIRB]

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

The information may be reviewed by WIRB®. WIRB is a group of people who perform independent review of research as required by regulations.

Your personal health information will be kept as confidential as possible under the law. However, your personal health information may no longer be protected by the privacy rule once it is disclosed to our associates, and may be shared with others.

This authorization will be good until [*EXPIRATION DATE]*

You may cancel this authorization at any time by sending a written notice to the principal investigator at the following address:

[PRINCIPAL INVESTIGATOR'S NAME]
[MAILING ADDRESS]

If you cancel this authorization, the principal investigator will no longer use or disclose your personal health information under the authorization for this study, unless he/she needs to use or disclose some of your personal health information to preserve the scientific integrity of the study. Information submitted before you cancel this authorization can still be used by the associates.

The Authorization for Use and Disclosure of Protected Health Information for research purposes is completely voluntary. However, if you do not sign this document you will not be able to participate in this study. If in the future you cancel this authorization, you will not be able to continue participating in this study.

COMPENSATION FOR INJURY

A. [If the Medical Sciences Campus is responsible for compensation in case of injury]

In the event of physical and/or mental injury resulting from this research study, you will receive medical treatment free of change at the University Hospital or any other hospital designated by the Chancellor or the Medical Sciences Campus of the University of Puerto Rico. The University

of Puerto Rico has no plans to provide any form of compensation directly to you. However, by signing this consent form you do not give up any legal rights.

B. [If the UPR MSC and the sponsor are responsible for the research participant and the sponsor will compensate the research participant in case of injury.]

If you suffer a physical or mental injury as a result of receiving the study drug or any medical procedures required by the study, you will be reimbursed by the sponsor for reasonable and customary fees and medical expenses actually incurred to treat such injury, but only to the extent such fees and expenses are not paid by your health insurance or governmental coverage. You will not be offered any financial compensation from the University of Puerto Rico Medical Sciences Campus. Your health insurance may not pay costs of treating a research related injury. No other provision has been made for payments of any other forms of compensation for a research related injury, such as for lost wages, lost time, or discomfort. By signing this consent form you do not give up any legal rights.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

FOR EXAMPLE:
Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent.

SOURCE OF FUNDING FOR THE STUDY

The study doctor is being paid by *[the sponsor] [or other wording, as appropriate]* to conduct this research.

QUESTIONS

FOR EXAMPLE:
If you have any questions about this study or your participation in this study, or if at any time you feel you have experienced a research-related injury or a reaction to the study medication, contact:

Dr. _____ at [*Phone]*

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500

E-mail: Help@wirb.com.

WIRB is a group of people who perform independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT

I have read the information in this consent form (or it has been read to me). All my questions about the study and my participation in it have been answered. I freely consent to be in this research study.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

By signing this consent form, I have not given up any of my legal rights.

_____

Subject Name

_____ _____

Signature of Subject Date

If Applicable

_____ _____

Signature of Legally Authorized Representative Date

_____

Authority of Subject's Legally Authorized Representative or Relationship to Subject (when applicable)

_____ _____

Signature of Person Conducting Informed Consent Discussion Date

---------- **Use the following only if applicable** ----------

If this consent form (addendum) is read to the subject because the subject (or legally authorized representative) is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form (addendum) and any other written information was accurately explained to, and apparently understood by, the subject (or the subject's legally authorized representative). The subject (or the subject's legally authorized representative) freely consented to be in the research study.

_____ _____

Signature of Impartial Witness Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.