GENERAL TEMPLATE INSTRUCTIONS:

Any template language highlighted in grey indicates language and/or instructions provided by the Institution. *[Bracketed italicized text in blue]* indicates alternative language or information to be filled in. Any wording in *red* represents instructions. All other language is WIRB standard wording.

PLEASE NOTE: WIRB is authorized to modify any section of this consent template **EXCEPT** the following sections; 1. Responsibility for Costs, 2. Compensation for Research Related Injury, and 3. Confidentiality and Privacy. Any changes to the aforementioned sections of the ICF require Drexel University HRP approval.

A listing of individuals authorized to consent subjects is no longer required.

Drexel University
RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:

PROTOCOL NO.:

WIRB® Protocol #
Institution Tracking #

SPONSOR:

INVESTIGATOR:

SITE(S):

When applicable please include the following, otherwise remove:
Hahnemann University Hospital
230 N. Broad Street
Philadelphia, PA. 19102

STUDY-RELATED PHONE NUMBERS:

Concise Summary of Key Information: (this is a two to three page summary of the trial). The final rule indicates that the prospective subject or legally authorized representative must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information. See detailed information in section 46.116 . Per the preamble, "the final rule does not adopt a requirement that certain information be included only in the appendices." "In general, our expectation is that this initial presentation of the key pieces of information will be relatively short.

Consent to Take Part in a Human Research Study

- Why is research performed?
- The consent is being sought for research and that the participation is voluntary?
- What will happen to me during the study?
- How long will I participate?
- Will I benefit from the study?
- Will Pariticpating expose me to risk?
- Do I have other options besides taking part in this study
- Will it cost anything to participate?
- Will I be paid to participate?

This section of the consent could, in appropriate circumstances, include a summary of relevant pieces of information that are explained in greater detail later in the consent form." The preamble also notes, however, that "information included at the beginning need not be repeated later in the body of the informed consent".

This is a long and important document. If you sign it, you will be agreeing to take part in a research study conducted by Drexel University and its researchers. You will also be authorizing Drexel University and its researchers to collect and share information about you. The research procedures are described in this document.

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.

SUMMARY

- You are being asked to be in a research study.
- Your decision to be in this study is voluntary.
- If you decide to be in this study and then change your mind, you can leave the study at any time.
- The [*drug/device/procedure*] in this study is experimental. Not all risks or side effects are known. Some of the side effects may be life threatening.
- The most common expected side effects and risks are explained in this consent form. Be sure to ask any questions you may have.
- You may receive placebo during this study. The placebo looks like the experimental drug but has no medication in it. If you agree to be in this research study, your medical records will become part of this research. They may be looked at or copied by the sponsor of this study or government agencies or other groups associated with the study.
- Your medical insurance [may/will] be billed for your routine care. Your insurance would then have access to your medical records and would know that you were in this study. Your insurance company may not pay for your routine care costs associated with a research study. Your participation could affect your insurance coverage.

- If you are injured in this study, your medical insurance will not be billed for any treatment you need to treat such injury.

More detailed information about this study is in this consent form. Please read it carefully.

INTRODUCTION

This research study is sponsored by [*enters sponsor's name*]. This sponsor is paying Drexel University to conduct this study.

PURPOSE OF THE STUDY

The purpose of this research study is to test an experimental [*drug/device/procedure*] called [*name of item*]. You are being asked to be in this study because you have [*disease/condition*] and may meet study requirements.

An experimental drug is also "investigational." This means the drug has not been approved by the U.S. Food and Drug Administration (FDA).

In this study, we will look at the safety of [*name of item*], how it affects your [*disease/condition*], and how well you tolerate [*name of item*]. *If appropriate:* It will be compared to placebo. The placebo will look just like [*name of item*], but has no medication in it. Both [*name of item*] and the placebo will be called "study drugs."

If a placebo is being used in this study, you cannot choose if you will be on [*name of item*] or placebo. This is decided by chance. You will have a [ ] chance *(e.g. equal or one in three, etc.)* of getting [*name of item*]. If a placebo is being used in the study, you will have a [ ] chance of receiving placebo. You and your study doctor may not know your assignment. If not known in advance, your study doctor can find this out if it needs to be known in an emergency.

You will be in this study about [*how long*]. Approximately [*how many*] subjects will participate in this study.

PROCEDURES

The following tests and procedures will be done at some or all of the study visits.

- Physical exam (visits __, __, __ and __)
- Blood and urine sample collection for routine tests (visits __, __, __ and __)
- Pregnancy test for all female subjects (visits __, __, __ and __)
- Electrocardiogram (ECG - tracing of the electrical activity of the heart) (visits __, __, __ and __)
- Blood collection for viral load (visits __, __, __ and __)
- etc.

The procedures listed below are experimental and are only done for the research:

- [*name of item, if any*] (e.g. angiogram)
- [More *name of items, if any*] etc.

RISKS AND DISCOMFORTS/CONSTRAINTS

The most serious possible side effects known of [*name of item*] are:

- [*Item of serious side effect here, if any*]
- Allergic reaction to [*name of item*] is possible. Serious allergic reactions can be life threatening.
- Etc.

The most common side effects known of [*name of item*] are:

- *Item of most common side effect here, if any*]
- *More Items of most common side effect here, if any*

Less common side effects known of [*name of item*] are:

- *Item of less common side effect here, if any*]
- *More Items of less common side effect here, if any*

Rare side effects known of [*name of item*] are:

- *Item of rare common side effect here, if any*]
- *More Items of rare common side effect here, if any*

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

UNFORESEEN RISKS

There may be side effects which are unknown at this time. Unexpected reactions, hazards, discomforts and inconveniences may affect the quality of life and may include life-threatening events or death.

If a treatment study:
Your [*disease, condition, symptoms*] may not get better or may become worse while you are in this study.

If a study drug is taken at 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.

REPRODUCTIVE AND PREGNANCY CONCERNS

Women who are pregnant or nursing a child may not participate in this study. In such a case, you must confirm that, to the best of your knowledge, you are not now pregnant, and that you do not intend to become pregnant during the study. We do not know what impact this drug will have on your fertility (your ability to conceive a child or impregnate a female). We also do not know what effects this drug will have on a pregnancy. You must use effective birth control throughout the course of this study and for [*how many*] months after that. If female, you must avoid getting pregnant. If you become pregnant while in the study, you must tell the study doctor as soon as possible. If male, you should avoid impregnating a female. You must use effective birth control throughout the course of this study and for [how many] months after that. While you are in this study, if your partner becomes pregnant you must tell the study doctor as soon as possible.

BENEFITS

Your [*disease/symptoms/condition*] may get better, but there is no guarantee of this. There may be no direct benefits to you from participating in this study.

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

ALTERNATIVE(S) TO PARTICIPATION

If you decide not to enter this study, there may be other treatments available. These include [*list of major drugs, therapies*]. The study doctor will discuss these with you. You do not have to participate in this study to be treated for [*disease, condition, symptoms*].
OR

This is not a treatment study. Your alternative is not to participate in this study.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Participation in this study is voluntary. You may refuse to be in the study or you may stop at any time without the loss of the care benefits to which you are entitled. However, you will be expected to follow the instructions provided by the research staff, in order to ensure your safety.

REASONS FOR REMOVAL FROM STUDY

You may be required to stop your participation before the end of the study for any of the following reasons:

a) A change in your medical condition;
b) Discontinuation of all or part of the study; or
c) Other reasons, including new information available to the investigator or harmful reactions experienced by you or other subjects in this study.

If you leave the study before the final regularly scheduled visit, the study doctor may ask you to make a final visit for some of the end of study procedures.

PAYMENT FOR PARTICIPATION

If using ClinCard, the language below must be included in the consent if not delete.

You will be paid $$ for each study visit completed. You will be paid a total of $$ if you complete all the scheduled study visits. If you do not complete the study you will be paid only for the study visit you completed. You will be paid using a Drexel University Clincard debit card and the funds will be loaded on the card within ___ working days of each visit. It is important that you do not lose the Drexel University debit card. If you lose the payment debit card the amount of $5.00 will be subtracted from your next study payment amount.

You will be paid $[enter amount] if you complete all scheduled study visits. If you do not complete the study, you will be paid $[enter amount] for each completed study visit.

If payments to subjects are $600 or more in a calendar year the following language is required.
Research Payments greater than $600.00 per year (or cash equivalent) are reported by the Institution providing payment, to the Internal Revenue Service for federal tax purposes. The level of reimbursement for this study is such that the IRS must be informed of the payments received. Additionally, a completed 1099 form will be collected.

RESPONSIBILITY FOR COSTS

You will not be charged for any tests specifically required for this research study, but you or your insurance company will be billed for tests or procedures that are considered "standard of care" and would have been part of your medical treatment if you did not participate in this study. These treatment costs include but are not limited to drugs, routine laboratory tests, x-rays, scans, surgeries, routine medical care, and physician charges.

Your health insurance company may not pay for these "standard of care" charges because you are in a research study. If your insurance company does not pay for costs associated with this research study that are considered standard care for your medical treatment, then you will be billed for these costs. You are responsible for paying for any insurance co-pays and any deductibles due under your insurance policy, and any charges your insurance company does not pay.

You will or will not be charged for study *drug or device* (pick which one if either is involved).

So that you do not have unexpected expenses from being in this study, ask your study doctor for a list of the tests or procedures that will be paid by the sponsor of the study.

COMPENSATION FOR RESEARCH RELATED INJURY

If you become ill during this study, please contact Dr. [name] at telephone no. (XXX) XXX-XXXX. If you require immediate medical attention, you should go to the nearest emergency room

or call 9-1-1. It is important that you inform all emergency medical staff that you are participating in this study.

If a "research related- injury" results from your participation in this research study, medical treatment will be provided at no cost to you and paid by the sponsor of the study. A "research related-injury" means injury caused by the product or procedures required by the research which you would not have experienced if you had not participated in the research study. You, or your medical insurance, will be responsible for other medical expenses resulting from your medical condition.

The university and hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge. However, you are not precluded from seeking to collect compensation for injury related to malpractice, fault, or blame on the part of those involved in the research, including the hospital.

It is important for you to follow your physician's instructions including notifying your study physician as soon as you are able of any complication or injuries that you experienced.

You will not be paid for any other injury- or illness-related costs, such as lost wages. You are not waiving any legal rights by participating in this research study.

If you are injured or have an adverse reaction, you should also contact Human Research Protection at 215-762-3944.

CONFIDENTIALITY AND PRIVACY

Add to this list other organizations that may have access to the subject's records such as the Food and Drug Administration, when the research if FDA-regulated, the Department of Health and Human Services, when the research is conducted or funded by DHHS, the sponsor, contract research organization, sponsor's agent and other collaborating institutions.

Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.

[If data or specimens will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the date or specimens will be retained. Institutional policy requires research related data to be retained a minimum of 3 years.

Health Information that will be collected

The following personal health information about you will be collected and used during the research study and may be given out to others: Your name, address, telephone number, date of birth;

- Personal and family medical history;

- Information from laboratory tests, blood and urine tests, x-rays, physical exams and other tests or procedures described in this consent form;
- Information learned during telephone calls, surveys, questionnaires and office visits done as part of this research study;
- Information in medical records located in your doctor's office or at other medical facilities you may have received treatment;

Who will see and use your health information within Drexel University.
The research study investigator and other authorized individuals involved in the research study at Drexel University will see your health information and may give out your health information during the research study. These include the research investigator and the research staff, the institutional review board and their staff, legal counsel, research office and compliance staff, officers of the organization and other people who need to see the information in order to conduct the research study or make sure it is being done properly. Your health information may be disclosed or transmitted electronically.

Who else may see and use your health information.
Other persons and organizations outside of Drexel University may see and use your health information during this research study. These include:

- Governmental entities that have the right to see or review your health information, such as the U.S. Office of Human Research Protections and the Food and Drug Administration
- Doctors and staff at the hospital where this research study will take place;
- Doctors and staff at other places that are participating in the research study;
- The sponsor of this research study and persons that the sponsor may hire to work on the research study.
- The contract research organization that is helping the sponsor manage this research study. The name of the organization is [*insert CRO name*];
- The Western Institutional Review Board® (WIRB®) WIRB is a group of people who perform independent review of research as required by regulations.

If your health information is given to someone not required by law to keep it confidential, then that information may no longer be protected, and may be used or given out without your permission.

Why your health information will be used and given out.
Your health information will be used and given out to carry out the research study and to evaluate the results of the study. Your health information will also be used if the sponsor may receive marketing approval for a new product or drug resulting from this research study.

Your information may also be used to meet the reporting requirements of governmental agencies.

If you do not want to give authorization (permission) to use your health information.
You do not have to give your authorization to use or give out your health information. However, if you do not give authorization, you cannot participate in this research study.

How to cancel your authorization.

At any time you may cancel your authorization to allow your health information to be used or given out by sending a written notice to Human Research Protection, Bellet Bldg. 7th Floor, 1505 Race Street, Philadelphia, Pennsylvania, 19102. If you leave this research study, no new health information about you will be gathered after you leave. However, information gathered before that date may be used or given out if it is needed for the research study or any follow-up.

When your authorization ends.
Select the most appropriate statement;

Your authorization to use and give out health information will continue until you withdraw or cancel your authorization.

OR,

Your authorization to use and give out your health information will end when the research study is finished.

After the research study is finished, your health information will be maintained in a research database. Drexel University will not re-use or re-disclose the health information in this database for other purposes unless you give written authorization to do so. However, the Drexel University Institutional Review Board may permit other researchers to see and use your health information under adequate privacy safeguards.

Your right to inspect your medical and research records.
You have the right to look at your medical records at any time during this research study. However, the investigator does not have to release this research information to you if it is not part of your medical record.

[OR]
You will not be able to look at your research records while you are taking part in this research study. Your personal information will be made available in an emergency if doctors need this information to treat you.

Use this paragraph for blinded or other studies where access will be denied
You can have access to your medical record and any research study information when the study is over. However, the researcher does not have to release research information to you if it is not part of your medical record.

Information about a Certificate of Confidentiality for this research. (As applicable)

[*Name of research site and investigator*] have received a Certificate of Confidentiality from the government which will help protect the privacy of research subjects. The certificate protects against the involuntary release of information about subjects collected during the course of this

research. The researchers involved in this study cannot be forced to disclose any information collected in this study in any legal proceedings.

However, the subject may choose to voluntarily disclose the protected information and this certificate do not prohibit such voluntary disclosure. Furthermore, the parties listed in the Confidentiality/Authorization section of this consent form may review our records under limited circumstances and this certificate does not prohibit such disclosure.

Please provide notice if these are relevant to protocol: (add N/A if not applicable)

1. You will/will not receive a share of financial gain resulting from commercial biospecimens profits.
2. Your clinically relevant research results will/will not be given to you by the research team (include conditions, eg. telephone, letter or in person).
3. This trial will/will not include whole genome sequencing.

Information about Genetic Information Nondiscrimination Act (GINA)

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research study.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information that we get from this research study when making a decision to hire, promote, or fire you or when setting the terms of your employment.

However, GINA will not protect you if you already have a genetic disease or disorder and does not prohibit discrimination on the basis of an existing genetic disease or disorder. In addition, this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Please Note: The GINA language section above MUST be included in your consent form if the research proposal involves ANY genetic evaluation of human tissue samples. If the proposal does not involve genetic analysis, this section may be omitted from the consent form.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

FDA regulations require that the consent form include disclosure that clinical trial information collected as part of the study will be entered into the clinicaltrials.gov databank. Therefore, any

study that needs to be registered in clinicaltrials.gov must include the above statement on the consent form. If you are not sure whether your consent form requires this disclosure, please contact Human Research Protection at 215-762-3944**.**

NEW INFORMATION

If new information becomes known that will affect you or might change your decision to be in this study, you will be informed by the investigator.

QUESTIONS

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. [*name*] at telephone no. (XXX) XXX-XXXX.

If you have questions about your rights as a research subject, you may contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue, SE Suite 120
Puyallup, WA 98374-2115
Telephone: 1-800-562-4789

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

You may also contact Drexel University Human Research Protection at 215-762-3944.

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 participate 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). I have initialed each page.
- I have been informed of the reasons for this study.
- I have had the study explained to me.
- I have had all of my questions answered to my satisfaction.

I freely consent to participate in this research study.

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

By signing this consent form I have not waived any of the legal rights which I otherwise would have as a subject in a research study.

_____ _____

Subject or Legally Authorized Representative Date

INSTRUCTIONS, DO NOT COPY:

[IF A SUBJECT IS UNABLE TO GIVE CONSENT, ONLY A LEGALLY AUTHORIZED (DURABLE POWER OF ATTORNEY FOR THE SUBJECT TO PARTICIPATE IN RESEARCH) FAMILY MEMBER, OR GUARDIAN, OR NEXT-OF-KIN CAN SIGN FOR THE SUBJECT.]

_____ _____

Investigator or Individual Obtaining this Consent/Permission Date

_____ _____

Witness to Signature Date

Drexel UNIVERSITY

Consent to Take Part in a Human Research Study