DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
503 ROBERT GRANT AVENUE
SILVER SPRING, MD 20910-7500

WRAIR #_____
Version _____, Date:_____

(DELETE THE TEMPLATE INSTRUCTIONS APPEARING IN BLUE TEXT, AND DELETE THE NON-APPLICABLE, OPTIONAL PARAGRAPH CHOICES IN BLACK PLAIN TEXT WHEN THEY DO NOT PERTAIN TO YOUR STUDY. YOU MAY ADD LANGUAGE ONLY WHERE INSTRUCTED.)

(Please change the title below to reflect the institution in which this document will be used. You may include multiple institutions for selected multi-site studies.)

(Use as appropriate:

- *This template is intended to include and standardize most options for research conducted throughout the WRAIR, but it may not address all your study's consent needs. Adapt this document as needed to fit your research design and the needs of your participant population.*
- *This consent document is written in second person and is designed to be completed by those individuals participating in the study. The language should be considered to refer to the research participant when a parent/guardian or legal representative is completing the form on the research participant's behalf [example: a child]. Therefore, this informed consent document will serve for adult or legally authorized representative [LAR] research consent.)*

Walter Reed Army Institute of Research
Consent for Research Participation

Title: [*Title*]

Sponsor: [*Name of Study Sponsor*]

Funder: [*Name of Study Funder*] [*if sponsor/funder are the same, delete this line*] [Include the funding mechanism]

Principal Investigator (PI): [*Name*], [*degree*] [*Institution (e.g., WRAIR)*]

Contact Info: [*Phone*] [*Email*]

IND/IDE Number: [*Number*]

You are being asked to take part in a research study. This study is supported/funded/conducted (include language that is appropriate) by the United States Department of Defense. The box below tells you important things you should think about before deciding to join the study. We will provide more detailed information below the box. Please ask questions about any of the information before you decide whether to participate. You may also wish to talk to others (for example, your family, friends, or your doctor) about this study, before agreeing to join.

(insert name, title or rank, please use degrees rather than the generic "doctor" and corps of local, IRB approved PI. If an over-all PI is involved, an additional line may be included below)

Please contact one of the below if you have any questions concerning the study or if you have any other questions or concerns.

PI NAME, credentials **(301) 319-number**

AI or Alternate Contact **(301) number**

After hours contact *(if applicable)*

Information in the box below should be written in an honest, conversational, non-technical tone, aimed at your specific recruitment population. Information specified in the Key Information Box need not be repeated later on in the document.

Key Information for You to Consider
• **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There are no penalties and you will not lose anything if you decide not to join or if after you join, you decide to quit. *[For challenge trials, this language will need to incorporate safety follow-ups]* • **Purpose**. We are doing this research to [*provide a brief description of why the research is being conducted, no more than 2-3 sentences*].

- **Duration.** Your part of the study will last [*expected duration*].
- **Procedures and Activities.** We will ask you to [*briefly highlight the key research activities/procedures*].
- **Risks.** Most studies have some possible harms that could happen to you if you join. In this study, we expect that [*describe the most important risks. Consider those most probable and/or highest magnitude of harm*].
- **Benefits**. We expect some benefits from this study, as well. For you, we expect [*insert direct benefits, or if no direct benefit to subject state no direct benefit but the researchers hope to learn/gain xyz*]. For [future participants, people with similar conditions, etc] we expect [potential outcomes of research].
- **Alternatives.** Instead of participating, you could [*note appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject. If there are no alternatives, state that, "Participation is voluntary and the only alternative is to not participate."*].

Why are we doing this research?

[*NOTE: If the full purpose is described in the key information summary above, this section may be deleted.*]

You are being asked to take part in this research study because *(explain, in lay terms, why the person was recruited for the study)*. The purpose of this research study is to learn about *(provide any background information, e.g., explanation of disease/condition under investigation in lay terms). Include a brief description of prior/related studies. Briefly explain why we need to conduct this research.*

(Include the following sections, as applicable, to your study:)

(for studies involving investigational test articles – drugs, devices, biologics, combination products, etc.)

This research study involves an investigational *(pick one: drug/device/biologic/combination product)* called *(name).* This means that the product has not yet been approved or cleared by the U.S. Food & Drug Administration (U.S. FDA) for *(pick one: treating/preventing/diagnosis/mitigation of) (disease or condition).* However, the U.S. FDA has approved its use in this research study to learn more about its safety and/or ability to work.

(for Phase I pharmaceutical studies)
This is an early human research study to examine the safety of this product. You are one of the first humans to receive this product. As a result, not all of the side effects are known. (*specify if this is a first in human study)*

(for Phase II/III pharmaceutical studies)
The safety of this product in humans has been tested in prior research studies. This research study will determine the proper amount of the product to give and test the ability of this product to work. Some side effects may not yet be known.

(for Phase IV pharmaceutical studies)
The U.S. Food & Drug Administration (U.S. FDA) sometimes requires drug manufacturers to follow up on new products once they become more widely used. This study is to follow up on *(insert product name).* This study is looking to see if there are any additional risks or benefits, and the best ways to use the product now that it is approved.

(for studies involving experimental interventions other than test articles – behavioral, educational, surgical, exercise, dietary, observational, etc.)

This study is looking at *(describe intervention). (Name of intervention)* has not been *(well-studied / studied before)*. This means that *(name of intervention)* is considered experimental for *(the treatment of [condition] / describe purpose of intervention)*.

(for local studies)
There will be *(number, or "no more than [number]")* people taking part in the study at *(list sites as applicable)*, over a period of *(number of days/months/years).*

(for multicenter studies)
There will be *(number, or "no more than [number]")* people taking part in this study overall, with *(number, or "no more than [number]")* participants to be enrolled at *(list sites as applicable)*, over a period of *(number of days/months/years).*

How long will I be in this research study?
[*NOTE: If all procedures/activities are described in the key information summary above, delete this section.]*

(Include the following sections as applicable to your study:)

We expect that your participation will last *(insert duration).*

(for outpatient studies)
During the study, you will have about *(number)* visits. We expect your time commitment for each visit to be *(for example, one hour per session)*.You may need to return to *(list sites)* every *(number of days/months/years).*

(for inpatient or other types of studies)
During the study, you will *(explain the expected duration of the participant's participation in the study, e.g., how much time and number of visits).*

What will happen if I decide to be in this research study?
[*NOTE: If all procedures/activities are described in the key information summary above, delete this section.]*

If you agree to be in this research, you will be expected to: *(Describe in reasonable detail all research and experimental procedures the participant will undergo. Describe any screening procedures used to qualify or select participants for enrollment such as inclusion and exclusion criteria. Do not include standard of care procedures that are part of the participant's clinical care). When necessary provide a length of time for procedures or surveys. Identify what procedures are experimental (if not obvious). For surveys/interviews, briefly describe kinds of questions asked or topics discussed. Describe the procedures chronologically using lay language, short sentences, and short paragraphs.*

(use this paragraph for studies involving randomization)
You will be randomly assigned to one of *(number)* groups, this is known as "randomization." Randomization is a process like flipping a coin *(or rolling a die if there are more than two groups)* and means you that you could be assigned to *(pick one: any/either)* of the groups. *(Describe each of the groups or treatment plans).*

(use this paragraph for studies using PLACEBO or Comparator and use the wording for the appropriate comparison)
You will have a one in *(number)* chance of being in the placebo/comparator group. A placebo is an inactive, harmless substance, like a sugar pill, that looks like the research study medication but contains no medication. For the comparator, describe what it is and why it has been chosen in layman's terms.

(include either single or double blind)

(Single Blind:)

This research study is a single blind study, which means that you will not know whether you are receiving the research study medication or a placebo/comparator, but the researchers will.

(OR)

(Double Blind:)
This research study is a double blind study, which means that neither you nor the research team will know whether you are receiving the research study medication or a placebo/comparator. In the event of an emergency, there is a way to find out which one you are receiving.

Add inclusion/exclusion criteria for Greater than Minimal Risk studies and studies with complex or narrow enrollment criteria (please ensure that these are summarized in layman's terms).
You may be allowed to participate in the study if you meet the following requirements: *[list].*

You are not allowed to participate in this study if any of the following criteria apply to you: [list].

What are my responsibilities as a participant in this research study?

If you agree to participate in this study, you will be expected to [list responsibilities such as informing the PI of withdrawing from research, communicating AEs/symptoms/etc with research team, arriving promptly to appointments, using approved methods of birth control, etc]. Section may be deleted if it does not add value to document.

What happens to the information *[and/or specimens]* collected for this research?
Information [*and/or specimens*] collected from you for this research will be used to *[explain*].

We may share your research data *(and/or specimens)* with other investigators without asking for your permission; it *[will/will not]* contain information that could directly identify you. *[If data must or will be deposited in a public or other repository, briefly describe.]* ***[OR]*** *[We will not share your research data with other investigators.]*

Add for all studies involving specimens: Your samples may be used for commercial profit, even if your name, birth date, or other identifying information are removed. You *[will/will not]* share in this commercial profit.

Add for studies involving specimens: Information that may be beneficial to your health [*will/will not*] be shared with you. Only the following types of results will be shared: (*list*).

(Research results): The overall results and findings from this study [*will/ will not*] be shared with you. *(if yes, explain how the results will be shared).*

Add for studies involving genetic research of specimens:
Some future research studies may include genetic testing of your samples. Using new technology, information about your DNA structure (genetic information) gained from your banked samples can be used to indicate risk for developing certain diseases. This genetic information is unique to you and may indicate changes in your future health status or life expectancy, or that of your children and other relatives. These discoveries could be stressful and cause psychological difficulties or family problems. It is also possible that during future research, people of your ethnic background may be found to be at more risk for certain diseases. *Include whether genetic test results will be returned to the participant, if yes, under what circumstances. Describe whether they can opt out.*

Add for all studies involving the collection of specimens: Whole genome sequencing [*will/will not*] be conducted on your samples in this study. Whole genome sequencing involves the analysis and description of your entire genetic code, or DNA. You genetic code is responsible for many of your physical characteristics and traits. While this genetic code is unique to you, half of your genes came from your mother and the other half from your father, which means that your other relatives share many of the same genes and traits. Through scientific tests of your whole genome, researchers can learn large amounts of information about you. This information when reviewed, can identify genetic conditions which may make it more likely for you to develop a disease. Also remember that your whole genome sequence is unique to you, like a fingerprint, so you can be identified by it. Similarly, because of the large percentage of genes you share with your relatives, your relatives may also be identified from your sample. As technology advances, this information will become more personally identifiable and we will be able to understand more about you simply from looking at the code. Any future use of your samples [*will/may/will not*] include whole genome sequencing.

For studies taking place in the United States only, include GINA language. Remove for OCONUS studies.
Release of personally identifiable genetic information may pose a possible risk of discrimination or increased difficulty in obtaining certain types of insurance for you and your family members. The Genetic Information Nondiscrimination Act of 2008 (Pub. L. 110-233) also known as “GINA” is a federal law that prohibits discrimination in health

insurance coverage and employment based on genetic information. However, GINA does not apply to employers with fewer than 15 employees. GINA's protections in employment do not extend to the US military. Nor does it apply to health insurance through the TRICARE military health system, the Indian Health Service, the Veterans Health Administration, or the Federal Employees Health Benefits Program. Lastly, the law does not cover long term care insurance, life insurance or disability insurance.

For clinical trials regulated by the US FDA, the following statement must be included: 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.

[*use of these two statements (former for opt-in broad consent; latter for mandatory specimen banking)* You have the option to allow your specimens be used for future research. *OR* By consenting to be in this study, your specimens will be saved for future research.] Future research using the specimens collected from you might include: [*list*]. You [*will/will not*]t be informed of what the testing may include and any research or clinically relevant results from the testing. *Include the following: need robust description for objectionable/controversial research; if participants have choice whether to opt out of receiving results or opt out of specific types of future research; description of identifiable private info or biospecimens used; whether sharing identifiable private info or biospecimens may occur and what types of institutions may receive; if info/biospecimens stripped of identifiers then need to clarify consent may not be withdrawn for future use; how to withdraw broad consent (or clarify why it is not possible); and include contact info for repository, if known. If the team commits to permitting a subject to discontinue use of the subject's identifiable biospecimens/data, state that identifiers will not be removed so this commitment may be honored.*

At the end of the study, your data/samples will be: *describe disposition plan. Example language:* Once the study is complete, your records will be kept in secure storage for a period of [*describe*], at [*location*]. Records will be maintained until it has been deemed no longer necessary to retain them by the study Sponsor [*insert study sponsor*], and then destroyed as per applicable regulations. Your specimens will be kept for [*time*], at [*location*]. Any future research using your data or specimens will require a research protocol and approval by an Institutional Review Board (IRB) (a committee responsible for protecting research participants) or other authorized official responsible for protecting human subjects in research studies. For instance, an IRB reviewed and approved this current study that you are taking part in. The data protections for privacy and confidentiality described in this document will apply to any future use of your stored data and samples.

What are the risks if I participate in this research?
[*NOTE: If all risks are disclosed in the key information summary above and/or are limited to breach of privacy and/or confidentiality, you may remove this section.*]

If you choose to take part in this study, there is a risk of:

(Describe any reasonably foreseeable risks or discomforts to the participant, particular to this protocol. Some estimate of the frequency and severity of the risk should be included (e.g., 10% chance of nausea, rare vomiting, etc). Consider psychological, legal, social, and economic risks as well as physical risks. Include brief discussion on how research team will mitigate risks).

(Include the following sections as applicable to this research study.)

(For venipuncture)
You may experience dizziness, have a bruise or be sore at the site where the needle drew blood. There is also a slight possibility of infection at the site where the blood is drawn.

*(For breach of confidentiality)*Although efforts are made to protect your research study records, there is always a risk that someone could get access to the personal information in your research records or other information researchers have stored about you.

(For reproductive health)
(name of product) [*has/has not*] been shown to cause birth defects.

(If "has," then add the following:)
The following birth defects have been observed: *(complete as appropriate to the protocol. If animal and/or human data is available on mutagenicity and teratogenicity, it should be presented so those participants will understand the danger of taking the drugs).*

This [*treatment/ procedure*] may cause risks to the [*fetus/embryo*] which are currently unforeseeable.

(OR, if there are no data on mutagenicity and teratogenicity, use the following statement:) It is not known whether (*medication*) can cause birth defects or other problems in an unborn child.

*(Add this paragraph if there is a risk to the fetus through **female** participants:)*
If you are a female who is able to become pregnant and you want to take part in this study, you should know that *(list the product/procedure)* might be harmful to (1) an unborn child if you are pregnant; or (2) an infant if you are breast-feeding. You must take a pregnancy test before you can participate in this study. You should not get pregnant or breastfeed while taking part in this study. The only completely reliable methods of birth control are not having sex or surgical removal of the uterus. Other methods, such as the use of condoms, a diaphragm or cervical cap, birth control pills, IUD, or sperm killing products are not totally effective in preventing pregnancy.

If you become pregnant or feel you might be pregnant, contact your personal physician and the Principal Investigator of this study listed in the Contact Information section at the end of this document.

*(Add this paragraph if there is a risk to the fetus through **male** participants, and reference the section above regarding use of birth control:)*
If you are a male who wishes to volunteer for this project, you should know that this *(list the product/procedure)* might be harmful to an unborn child if your partner(s) should become pregnant. Therefore, you should not father a child while in this study. [*add contraceptive requirements here*]

(For interventional studies, or as otherwise applicable:)
There may also be other risks of taking part in this study that we do not yet know about.

How will my privacy and data confidentiality be protected?
We will take measures to protect your privacy. Even with these measures, we can never fully guarantee your privacy will be protected. We will try our best to protect your privacy by doing the following:
• (*Discuss steps that you will take to protect participant privacy, (e.g., conduct research in private setting and/or other space consideration, security parameters of online survey platforms*).
• (*Discuss any known limits to protecting privacy (e.g., group participation and knowing who other participants are, research setting, etc.)).*

To help ensure this, your name and any identifiable information (for example, your address or social security number) will be removed from study files and your lab samples and be replaced with an identification code that consists of numbers and letters. Different codes may be used for you during the course of the study. Only the study investigators, study coordinators, research monitor and representatives from

certain agencies (described below) will be allowed to know which codes belong to you, and to have access to your study information.

Your study files will be kept in a safe, secure storage area at [location] for the duration of the study.

While we will do our best to protect your information there are some cases where we cannot guarantee complete confidentiality.

(*For studies that have been issued a Certificate of Confidentiality*), NIH has specific criteria for disclosure to participants. Studies that involve collection or use of identifiable sensitive information may have a Certificate of Confidentiality through NIH either because:
• *A Certificate of Confidentiality was automatically issued with the terms and conditions of the award (only studies funded on or after December 2016*) – **OR-**
• *The research team has applied for and obtained a Certificate of Confidentiality from NIH.*

(*NIH expects researchers tell participants about the protections afforded by the Certificate of Confidentiality. NIH provides the sample language below which should be adapted to the study participants and subject matter of the research*):
This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

(*Additionally include the following language as applicable*):
The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by [*THE AGENCY*] which is funding this project or for information that must be disclosed in order to meet the requirements of the federal U.S. Food and Drug Administration (US FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information

released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

(*Language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws*):
The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others].

(Language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants):
The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document [*restate what will be disclosed, such as including research data in the medical record*].

We may report [*describe what is reported*] to authorities, to prevent serious harm of yourself or others.

- We are required to report information regarding certain infectious diseases (like HIV or AIDS and viral hepatitis) to the local health department. If your blood tests show that you have one of these infections, we will report this information to the health department, and they may need to interview you to get more information. This may cause you some distress, and could affect your personal and professional relationships. We will provide trained counselers to discuss test results and refer you for further care as required.
- For volunteers who are in the military, information bearing on your health may be required to be reported to appropriate medical or command authorities. *[Explain what might need to be reported, e.g., results of tests for substance abuse, information about suicidal or homicidal behaviors, etc.]*
- Representatives from the following agencies may have access to review research records as part of their responsibility to protect humans in research and oversee the quality of the research efforts. As government agencies, they must also maintain confidentiality of your records within the limits of the law.
  - The Study Sponsor, [*name*]
  - The WRAIR Institutional Review Board (IRB)
  - U.S. Army Medical Research and Development Command (USAMRDC)
  - The US Food and Drug Administration [*add as applicable*]

– [others, *i.e., other IRBs, regulatory bodies, i.e. EMA*]

Please remember that even though we are doing our best to protect your information, we can never fully guarantee confidentiality of all study information.

What are the possible benefits from this research?

[*NOTE: If all benefits are disclosed in the key information summary above, this section may be deleted*. Please note that per 10 USC 980, if this is experimental research there needs to be a benefit to each individual subject if they cannot consent for themselves.]

(Include one of the following statements as applicable to this study:)

By taking part in this study, you may expect some of these benefits *(complete as appropriate to the protocol. Note that payment given to the participant for participation is not a "benefit" to be listed in this section).* There is no guarantee, however, that you will benefit from being in this research.

(OR)

You will not receive a benefit by taking part in this study. There is a chance that in the future, other people may benefit from the information learned during this study. The possible benefits to others are *(describe how other may benefit in the future from the study)*.

What other choices do I have besides participation in this research?
[*NOTE: If the alternative is to "not participate" or these have been fully disclosed in the key information summary above, you may remove this section.]*

It is your choice to participate or not to participate in this research.

(For interventional studies)
There may be other options for *(treating your condition, etc.).* Alternative treatments and/or procedures that may be available to you include: *(list all alternative treatments - these may include other treatments, e.g. chemotherapy, radiation therapy, or hormonal therapy).* You should talk with your personal doctor (primary care physician) *(if applicable)* about these options.

(AND if applicable)
There may be other research studies involving experimental treatments researching the same [*topic of interest]* that you may prefer over this study.

(If applicable for products with US FDA approved indications, add:)
The product involved in this research study may also be available through your personal doctor without taking part in this study.

Will I be paid to take part in this research study?

No, you will not be paid for participating in this study.

(OR)

Yes, for your participation, you will receive: *(explain details of compensation such as type/form, to include meals/transportation/childcare, etc., amount, timing, and pay. Note that federal personnel participating as human participants in DoD-conducted research while* ***on-duty*** *may only be compensated up to $50 per blood draw for research meeting 24 USC §30 criteria, and may not otherwise be compensated for general research participation.)*

Add military and civilian restrictions, such as approval from the chain of command, as applicable: Federal and military regulations place limits how much and for what federal civilian employees and active duty research volunteers may be compensated, if participating while on duty hours. If you are a federal civilian employee or active duty research volunteer and you participate in this research during duty hours, you may receive up to $50 per blood draw only. All federal personnel, both military and civilian, will need to be on leave or off duty to be fully compensated for their participation in the study.

Active duty military volunteers will require approval from their supervisor through their Branch Director using the Statement of Supervisor's Approval, which will be provided to you.

Other than medical care that may be provided and any other payment specifically stated in this informed consent, there is no other compensation available for your participation in this research study; however, you should also understand that this is not a waiver or release of your legal rights.

[*discuss what compensation may be kept/prorated if subject withdraws from research or is terminated*]

Are there costs for participating in the research?

No, there are no costs to you for taking part in this research study.

(OR)

Yes, there are costs to you for taking part in this research study. These include *(explain, such as child care costs, travel costs, lost income from time off work, etc.).*

(AND if applicable)

You will be reimbursed for these costs as follows: *(explain amount, timing, and payor)*

(OR)

You will not be reimbursed for these costs.

Are there disclosures of financial interests or other personal arrangements from the research team?

(Identify here any financial interests or other personal arrangements that the INSTITUTION, the research team members, or their immediate family members, might have with this study, with its sponsors/funding sources, with the manufacturer of the tested drug, device, biologic, combination product, or medical supply, or with a storage bank where any study specimens could be subsequently sent. Such interests may include but are not limited to: direct/indirect money payments; transfers of value; ownership interests; significant investment interests; or proprietary rights in the tested product. Example: A member of the research team, (name), is a paid consultant to the company sponsoring or paying for this study.)

(AND)
The sponsor of this research study has agreed to pay you back *(list INSTITUTIONs here)* for some of the costs related to your participation in this study. *(Explain; specify if any related research-related injury costs are reimbursed/covered)*

(AND)

Your participation in this research study will provide financial benefit to the study sponsor and to the research program of *(list names here). (Explain)*

What happens if I am injured as a result of this research? [Note: This section is not required for minimal risk studies where there is no product, device, etc.; therefore, this section can be omitted for such studies]

If you are injured because of your participation in this research and you are a Department of Defense (DoD) healthcare beneficiary (e.g. active duty in the military, military spouse or dependent, retiree), you are entitled to medical care for your injury within the DoD healthcare system, as long as you remain a DoD healthcare beneficiary.

[For CONUS research studies; revise as applicable to your study; for OCONUS, describe care available to subjects] If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are entitled to medical care for your injury at DoD hospitals or clinics, but care for your injury may be limited to a given time period, and your insurance may be billed It cannot be determined in advance which DoD hospital or clinic will provide care. If you obtain care for research-related injuries outside of a DoD hospital or clinic, you or your insurance will be responsible for medical expenses.

[revise as applicable to your study] Transportation to and from hospitals or clinics will not be provided. No reimbursement is available if you incur medical expenses to treat research-related injuries. No compensation is available for research-related injuries. You are not waiving any legal rights.

If you believe that you have sustained a research-related injury, please contact the PI, [*name and contact info*] or the [*alternative contact, role in study, and contact info*]. (Add as applicable): In addition, an emergency contact card will be provided to you with numbers to contact at any time.

What happens if I withdraw from this research?

You may withdraw from this study at any time. If you choose to leave the study, data collected prior to your withdrawal [*will/will not*] be used by the study. You will be asked for your permission to use any [*data/specimens/other data sources*] that you have provided up to that time.

You may withdraw your consent at any time and stop participating in this research study. Leaving the study will not impact your ability to receive care or any other benefits that you would have received otherwise. Should you choose to withdraw, you should

(state withdrawal procedures to include returning all research study material. NOTE: If further testing is recommended after the participant's request for withdrawal, you must explain why the tests are necessary for the participant's welfare). If you do not follow these procedures, you may experience *(state health risks if research study withdrawal procedures are not followed)*.

(*Only add this when HIPAA applies*): Please note that withdrawing your consent to participate in this research does not fully revoke your HIPAA (Health Insurance Portability and Accountability Act) Authorization Form to use/disclose your protected health information. To make that revocation, please send a letter to the Principal Investigator as discussed in the HIPAA Authorization Form.

The Principal Investigator, [*name*], may decide not to allow you to continue participating in this study under the following conditions:

- If you develop health conditions that would make it dangerous to you or others if you were to continue participating
- If other situations or conditions arise that would make participation harmful to your own health,
- If you fail to comply with the procedures as outlined in this form.
- *(Other as applicable)*

(Include the following paragraph if applicable for a research study involving experimental product)

The sponsor of this research study may end the research study and/or your participation in this research study for safety reasons, funding reasons, or if the product receives the approval of the U.S. Food and Drug Administration. There is no guarantee that the product you will receive during this research study will continue to be available through your healthcare system.

We will tell you if we discover any significant or new information during the study that may affect your health and willingness to continue participation.

Who can I contact if I have questions about my rights as a research participant?

If you have questions about your rights as a research volunteer in this study, you may contact the Human Subjects Protection Branch, Walter Reed Army Institute of

Research, 503 Robert Grant Avenue, Silver Spring, MD 20910, phone number 301-319-9940, and email usarmy.detrick.medcom-wrair.mbx.hspb@health.mil.

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to *["choose not to participate in any study activity or" if applicable]* completely withdraw from continued participation at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If there is any portion of this document that you do not understand, ask the investigator before signing the form. Signing this form means that you consent to participate in this research, at this time.

A signed and dated copy of this document will be given to you.

(Signature blocks for participant and individual administering consent must be part of all forms. Other signature blocks will be included when appropriate, as when the research study involves children, surrogate consent, etc., see throughout form)

(Required for future use) **Please initial the sentences that reflect your choices, and then sign below:**

_____ I do not authorize the storage of data collected as a part of this study for use in future research studies.

_____ I authorize the storage of data collected as a part of this study for use in future research studies.

With regard to future research studies done on stored data that has a link to my personal identity.

_____ I do not wish to be notified by investigators in the event of research findings of possible importance to my family members or myself.

_____ I wish to be notified by investigators in the event of research findings of possible importance to my family members or myself. I agree that my current Principal Investigator may use any appropriate identifier (Social Security Number, country ID number, etc.) to locate me in the future.

(Required for future use) **Please initial the sentences that reflect your choices, and then sign below:**

_____ I do not authorize the storage of my biological specimens for use in future research studies.

_____ I authorize the storage of my biological specimens for use in future research studies.

(Add the election below if applicable, for specimens with identifiers, including coded specimens)

With regard to future research studies done on my biological specimens kept at the storage bank:

_____ I do not wish to be notified by investigators in the event of research findings of possible importance to my family members or myself.

_____ I wish to be notified by investigators in the event of research findings of possible importance to my family members or myself. I agree that the investigators conducting this study may use my social security number to locate me in the future.

SIGNATURE OF PARTICIPANT

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Permanent Address of Participant

(Use the following signature blocks for representative, parents, and guardians, only if applicable)

****

Your signature below indicates you are legally authorized to act on behalf of the participant, and have read this document. You will receive a copy of this document. *(The Principal Investigator is responsible for confirming that an individual is a Legally Authorized Representative based on local and state laws.)*

SIGNATURE OF LEGALLY AUTHORIZED REPRESENTATIVE

(Add thumbprint boxes if illiterate subjects will be enrolled in the study.)

_____
Printed Name of Legally Authorized Representative

_____
Relationship to the Participant

_____ _____
Signature of Legally Authorized Representative Date

(Remove the witness signature if this study is conducted under ICH GCP. Determine if your institution requires witness to the entire consent process or only witness to the final signature.)

SIGNATURE OF WITNESS TO CONSENT/CONSENT PROCESS
(This individual can be a relative of the participant, but cannot be an individual involved with the research study.)

_____
Printed Name of Witness

_____ _____
Signature of Witness Date

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SIGNATURE OF INDIVIDUAL ADMINISTERING CONSENT
(Can only be signed by an investigator or staff approved to administer consent)

_____
Printed Name of Administering Individual

_____ _____
Signature of Administering Individual Date

Quality Control conducted by _____ on _____.
name date

_____
Signature