***GENERAL INSTRUCTIONS:***

* *Enter your information in the spaces provided.*
* *Delete All Instructional Text In Blue Italics*
* *Delete the reference to the template version in the footer.*
* *Version Date - add to top left (header).*

***Recommendations for making the consent more MEANINGFUL so the subject has the NECESSARY information to make an informed decision about participating:***

* *Present the information in SUFFICIENT detail.*
* *Highlight precautions or restrictions that might impact the subject’s decision about participating (e.g. caffeine, alcohol, exercise, fasting).*
* *Consider including detailed procedures or schedules as an appendix for participants to refer to, rather than within the body of the consent.*
* *Organize the information to FACILITATE the subject’s understanding of the research.*
* *Use concise, PLAIN language throughout the document.*
* *Use short sentences.*
* *Use the second person (you, your) throughout to address the study participant.*
* *Use bullets, photos, and diagrams to improve participants’ understanding (“a picture is worth a thousand words”).*

*[Insert name of institution here]*

**CONSENT TO PARTICIPATE IN RESEARCH**

Title of Protocol:

[*If the study involves using different consent forms for different groups or research phases, identify the group or phase as a subtitle here. If the title contains very technical language, consider adding a 2nd title in language appropriate to the target population.]*

Principal Investigator:

Sponsor:       *This refers to a FDA-regulated Sponsor (Only include for studies with an IND or IDE or for which a company takes responsibility and initiates a clinical investigation).* ***FUNDING SOURCE DOES NOT NEED TO BE LISTED HERE. DELETE THIS SECTION IF NOT APPLICABLE****.*

Introduction: You are being asked to participate in this research study because      . *[Explain how or why the person was identified as a potential participant or meets basic eligibility criteria, e.g, “you are in basic training,” “you have normal hearing”]*.You do not have to take part in this research. It is your choice.

If you are providing consent as a legally authorized representative (LAR), “you” or “your” refers to the research participant.

The table below summarizes some **key** points to think about. After reading this summary, if you think you might be interested in participating, read the rest of the consent form for more details about the study.

|  |  |
| --- | --- |
| **RESEARCH SUMMARY** | |
| **Informed Consent** | It is important that you understand this research study so that you can make an informed decision. This process is called informed consent.   * Please ask questions about anything you do not understand. * Feel free to talk with your family, friends, or others before you decide. * After your questions have been answered, you will be asked if you want to participate. If you agree, you will sign this consent form. * You will be given a copy of this form to keep. |
| **Voluntary Participation** | You do not have to take part in this research. It is your choice. You can also choose to stop participating at any time during the study. |
| **Purpose** | [*Explain research questions and purpose succinctly in lay language].* |
| **Duration** | You will be in this study for about [*Insert duration].* |
| **Procedures** | While you are in the study, you will *[Present key study procedures clearly and succinctly in a bulleted format]*   * *Not all study procedures need to be stated. List the procedures that are likely to be* ***important factors*** *in deciding whether or not to participate.* * *Consider listing in order of importance rather than chronologically.* * *Include lifestyle restrictions (e.g., no caffeine during the study or no smoking or alcohol) and/or precautions.* * *Consider use of* ***BOLD*** *font to emphasize key points.* * *Include large time commitments and/or overnight stays.* * *When applicable, state that photos/videos will be obtained.* |
| **Drugs/Devices**  ***[DELETE ROW IF NOT APPLICABLE]*** | The drug(s) used in this study is/are: [*Insert drug name(s)that are the subject of the research]*  *Or*  The device(s) used in this study is/are: *[Only list if the device is the subject of the research. Use lay terms rather than listing device name and model number.]*  *[If applicable, include a statement that the product(s) is (are) investigational and not approved by the FDA.]* |
| **Risks** | The **main** risks from being in this study are:   * [*Insert a bulleted list of risks, focusing on the most common and/or significant]* * [*If appropriate, may add*: Steps to lessen the risks are described later in this consent form.*]* |
| **Benefits** | *[Describe the reasonably expected benefits to the participant. If there is no benefit to the individual participant, clearly state so.]* |
| **Alternatives [DELETE ROW FROM SUMMARY TABLE IF NOT AN INTERVENTIONAL STUDY]** | *[Briefly describe the main alternatives to participation on this study].* |
| **Payment** | You will not be paid for your participation in this study.  *Or*  You will be paid for your participation in this study.  *[Do not discuss details in summary table, but do specify if certain groups will be paid and others will not].* |

**WHY IS THIS RESEARCH BEING DONE?**

The purpose of this research is      . [*Explain in plain language.]*

*[Provide a brief explanation (2-3 sentences) to support the need for conducting this study.]*

*[If relevant to the purpose of the study, provide brief information about prior, similar, or related research (e.g., earlier phase clinical trials).]*

**WHAT WILL HAPPEN DURING THIS RESEARCH?**

If you agree to participate in this research, you will be asked to do the following:

*[SUCCINCTLY explain all procedures in sequential order. Include screening evaluations, the number of study visits, when and where the visits will occur, how long visits will take, and what procedures will occur at each visit. Clearly distinguish procedures done for research purposes from those done as part of standard clinical care/treatments or other activities that would occur regardless of participation)].*

*[If applicable, describe any study articles that will be used (drugs, placebos, devices, dietary supplements, etc.). If giving an investigational drug (or a dietary supplement used as a drug), biologic, or device, include a statement that the product is investigational and not approved by the FDA.]*

*[If the protocol involves more than one study arm or treatment group, explain the differences between the groups and how participants will be assigned to a group.]*

*[For randomized studies, explain the randomization process, including the chance of being in each group and whether participants and/or researchers will know the group assignments.]*

*[When applicable (such as for treatment studies), address the implications of participating in a randomized study; e.g., their treatment assignment will be based purely on chance rather than their or their physician’s preference; none of their care providers or the research team will know which group they are in; no other treatment options can be pursued while receiving the study treatment, etc.]*

***[If the study involves the collection of biospecimens (e.g, blood, urine, tissue), federal regulations require that participants be informed whether the research will or might include whole genome sequencing. IF NO BIOSPECIMENS WILL BE COLLECTED, DELETE THE REMAINING PARAGRAPHS IN THIS SECTION.***

*-If no genetic testing at all will be performed, state:* No genetic tests will be performed in this study on your *[type of specimens collected (e.g., blood specimens, urine specimens].*

*-If any genetic testing (whole genome or not) will be performed, include the following:* This study will collect samples of material from your body, including *[urine, blood, tissue, cells].* This material contains your genetic information. Genetic information is carried by a chemical called deoxyribonucleic acid (DNA) that is copied and inherited by future generations. Almost every cell in a person’s body contains DNA. DNA is like a big instruction book which tells the body how to grow and develop. Instructions are contained in segments of DNA called genes. The complete set of genes is called the whole genome.

Genetic studies may look at patterns of how genes are inherited, markers that predict how someone will recover from a disease or injury, like traumatic brain injury, or if someone is likely to get a particular disease, like breast cancer. This information is contained in your DNA, which consists of four letters (or base pairs). The order of these letters determines a person’s genetic code.

*- For whole genome testing, add:* In this study, we will look at your entire set of genes. *Summarize the purpose of the whole genome sequencing]*

*OR*

*-For other genetic testing (not whole genome), add:* In this study, we will not look at your entire set of genes. *Summarize what genetic testing will be performed (e.g., looking for a certain biomarker) and for what purpose.*

**HOW LONG WILL I BE IN THE STUDY?**

*[State the total length of time for participation.]*

**WHAT PRECAUTIONS DO I NEED TO TAKE? [DELETE HEADING AND SECTION IF NOT APPLICABLE]**

*[Address precautions to be taken by the participant before, during or after study participation, e.g., foods/medications that should/should not be taken while on study, birth control requirements or recommendations for women and for men.]*

**HOW MANY PEOPLE WILL BE IN THE STUDY?**

*[State the number of study participants expected to be enrolled at this site. For multi-site studies, state the number to be enrolled at this site and the total number of participants to be enrolled at all sites.]*

**WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**

      [*Describe any reasonably foreseeable study-related risks and/or discomforts to the participant. Also include known, serious risks even if they have a low probability of occurring.*

*When appropriate to the study, address:*

* *Risks associated with loss of privacy and/or breach of confidentiality*
* *Psychological, social, economic or legal risks that might result from participating in the research*
* *A statement that the treatment or procedure may cause risks to the participant which are unknown at this time*
* *A statement that the treatment or procedure may cause risks to germ cells (e.g., sperm or eggs), embryo, or fetus that are unknown at this time]*

*When appropriate, describe the measures in place to mitigate the risks of study procedures.*

*Consider providing the information in a table with the likelihood of occurrence (as applicable) to facilitate understanding.*

**WHAT ARE THE POSSIBLE BENEFITS FROM BEING IN THIS RESEARCH?**

*[Describe the anticipated benefits to the participant that may result from participation in the research. If there is no benefit to the individual participant, clearly state so. Do NOT include payment as a benefit, address compensation below in the WILL I BE PAID TO TAKE PART IN THIS RESEARCH section.]*

*[Describe the anticipated benefits, if any, to science or society/community.]*

**WHAT IF UNEXPECTED INFORMATION IS LEARNED ABOUT MY HEALTH? [DELETE HEADING AND SECTION IF NOT APPLICABLE]**

*[Explain the plan if research procedures may result in discovery of unforeseen or incidental findings, to include whether the subject will be informed and by whom, and whether their provider will be informed.]*

**WILL RESEARCH RESULTS BE SHARED WITH ME?**

*[State whether research results will be disclosed to participants, and if so, under what conditions. State whether and when clinically relevant research results will be shared with the subject (e.g, improvement in subject’s burn injury in response to a new therapy). If no results will be provided, state so.]*

**WHAT ARE MY OTHER OPTIONS IF I DO NOT PARTICIPATE IN THIS STUDY?**

*[Describe any relevant alternative procedures or courses of treatment that are available to the participant. In some cases, it may be appropriate to state the only alternative is not to participate in the study.]*

**WILL I HAVE TO PAY FOR ANYTHING IF I TAKE PART IN THIS RESEARCH?**

*[Describe any costs that the participant may incur as a result of participation, for example travel, parking, meals; state whether any of the incurred costs will be reimbursed. If applicable, state what costs will be covered by the Sponsor. If there are no anticipated costs, state so.]*

**WILL I BE PAID TO TAKE PART IN THIS RESEARCH?**

*[State the amount of compensation that participants will receive. If the study involves multiple visits, address the plan if the participant does not complete the study; consider use of a table when compensation is prorated. If there is no compensation, state this plainly.]*

*[Explain that biospecimens (even if identifiers are removed) may be used for commercial profit, and state whether or not the participant will share in this commercial profit* **DELETE IF NOT APPLICABLE***].*

**WHAT HAPPENS IF I AM INJURED AS A RESULT OF TAKING PART IN THIS RESEARCH? *[DELETE HEADING AND TEXT FOR MINIMAL RISK RESEARCH]***

If at any time you believe you have suffered an injury or illness as a result of participating in this research, please contact       [*Identify the local PI* and *include current daytime telephone numbers and addresses. If appropriate, include night/emergency telephone numbers. If participants are from wide geographic areas, consider a toll-free number].*

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

If you are injured because of your participation in this research and you are not a DoD healthcare beneficiary, you are entitled to 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.

For DoD healthcare beneficiaries and non-DoD healthcare beneficiaries: 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 you have sustained a research-related injury, please contact the Principal Investigator (PI). If you have any questions, please contact the Pl.

**HOW WILL YOU PROTECT MY PRIVACY AND THE CONFIDENTIALITY OF RECORDS ABOUT ME?**

*[Describe measures to protect participant’s privacy during study procedures and when communicating about the study].*

*[Describe all strategies you will use to ensure that unauthorized individuals do not gain access to the participant’s study records (protect confidentiality)]*

*[If screening involves drug screening or testing for reportable diseases, explain the extent to which data will be kept confidential. Address local or federal reporting requirements, if any. Inform the participant about availability of follow-up or referral for treatment.]*

Authorized representatives of the following groups may need to review your research and/or medical records as part of their responsibilities to protect research participants:      *[Identify all agencies and institutional authorized representatives who may inspect research records:]*

* U.S. Army Medical Research & Development Command Institutional Review Board responsible for review and oversight of human research
* DoD and other Federal offices charged with regulatory oversight of human research
* *[Your institution’s human research protections office]*
* *[Food and Drug Administration,* ***ONLY IF APPLICABLE]***
* *[The Sponsor,* ***ONLY IF APPLICABLE****]*

***[If participants’ IDENTIFIABLE PRIVATE INFORMATION or IDENTIFIABLE BIOSPECIMENS will be collected as part of the study, include one of the following statements regarding future research:***

Once information that personally identifies you is removed from your data or specimens, then your data or specimens may be used for future research studies or given to other researchers for future research studies without your permission to do so.

*or*

Your data or specimens collected as part of this research will not be used for future research studies or given to anyone else for future research studies, even if all information that personally identifies you is removed.

*[if neither of these statements fully describes the plans for future use, include an additional statement clearly informing participants of the plan for future use, including the maintenance or removal of identifiable information]*

*[When military personnel will be recruited and enrolled, include the following:* Complete confidentiality cannot be promised for military personnel, because information bearing on your health may be reported to appropriate medical or command authorities. *Explain what might need to be reported, e.g., results of tests for substance abuse]* ***DELETE IF NOT APPLICABLE****.*

*[When genetic analyses will be conducted, include the following:* You should know that a Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally prohibits health insurance and employment discrimination based on your genetic information.

• Health insurance companies and group health plans may not use your genetic information

when making decisions regarding your eligibility or premiums.

• GINA's health insurance protections do not apply to members of the military who receive their healthcare through Tricare, to veterans who receive their healthcare through the Veterans' Administration, or to Federal employees who get their care through Federal Employee Health Benefit Plans. However, these groups may have policies in place that provide similar protections.

• Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment. While GINA's employment protections do not apply to military members and Federal employees presently an Executive Order protects federal employees from genetic discrimination in employment and the military has its own policies in place that may protect against genetic discrimination.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.] ***DELETE IF NOT APPLICABLE****.*

*[If Volunteer Registry Datasheets are required (USAMRDC-conducted GTMR research unless a waiver has been obtained), include the following:* The U.S. Army Medical Research and Development Command (USAMRDC) keeps information about volunteers participating in USAMRDC-conducted research in a confidential “Volunteer Registry Database”. The information includes your name, address, social security number, the name of the study you participated in and the dates of your participation. This information helps the USAMRDC be able to inform volunteers if new risks or important information are found. The information will be stored at the USAMRDC for a minimum of 75 years.] ***DELETE IF NOT APPLICABLE***

***FOR FDA-REGULATED RESEARCH ONLY:*** *In accordance with 21 CFR 50.25(c), the statement below must be reproduced word-for-word in informed consent documents for applicable clinical trials. "Applicable clinical trials" generally include interventional studies (with one or more arms) of drugs, biological products, or devices that are participant to FDA regulation, meaning that the trial has one or more sites in the U.S, involves a drug, biologic, or device that is manufactured in the US (or its territories), or is conducted under an investigational new drug application (IND) or investigational device exemption (IDE).*

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 results. You can search this Web site at any time. ***DELETE IF NOT APPLICABLE***

**WHAT IF I DECIDE NOT TO PARTICIPATE IN THIS RESEARCH?**

It is your choice whether you want to participate in this research. You can choose not to be in the study now without any penalty or loss of benefits to which you are entitled.

If you decide to participate, you can stop taking part in this research at any time without any penalty or loss of benefits to which you are entitled. Deciding not to participate now or withdrawing at a later time does not harm, or in any way affect, your [*medical care or*] future relationships with       [*name of the research institution]*.

*[Explain the consequences of a participant's decision to withdraw from the research, if applicable, including any adjustment in compensation that may occur. When withdrawal from the study may have deleterious effects on participant health or safety, explain any withdrawal procedures that are necessary to complete to protect participant safety. Explain whether data collected to the point of withdrawal will be used]* ***DELETE IF NOT APPLICABLE.***

**WHAT COULD END MY PARTICIPATION IN THE RESEARCH?**

*[State reasons the Principal Investigator might remove the participant from the study, for example study termination by the sponsor, FDA, or the IRB; the participant not following investigator instructions.]* ***DELETE IF NOT APPLICABLE.***

**WHAT IF ANY NEW INFORMATION IS FOUND OUT? *DELETE IF NOT APPLICABLE*** *(e.g., for some single interaction research studies).*

During the course of the research, the investigators will tell you of any new findings that might cause you to change your mind about continuing in the study. If you receive any new information, the investigators will obtain your consent to continue participating in this study.

*[Describe the plan for disseminating any new information to participants]*

**WHO SHOULD I CALL IF I HAVE QUESTIONS OR CONCERNS ABOUT THIS RESEARCH?**

If you have questions about the research at any time, you should contact       *[identify an appropriate person to contact, including their name and working telephone number(s) with active voicemail.]*

If you have questions regarding your rights as a research participant, you may contact the HQ USAMRDC IRB Office at 301-619-6240 or by email to usarmy.detrick.medcom-usamrmc.other.irb-office@mail.mil. *[may include an institutional contact such as the HPA, in addition to the IRB]*

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**ADDITIONAL OPTIONS: *DELETE IF NOT APPLICABLE***

***[If the protocol involves contacting participants about participation in future research studies, or additional optional research procedures include a section for the participant to agree or not for each item].***

\_\_\_\_\_\_Yes \_\_\_\_\_\_No Initial your choice

By signing below, I agree that I have been provided time to read the information describing the research study in this consent form. The content and meaning of this information has been explained to me. I have been provided with the opportunity to ask questions. I voluntarily consent to participate in this study.

By signing this form, I have not given up any of my legal rights as a research participant.

|  |
| --- |
| **SIGNATURE OF RESEARCH PARTICIPANT** |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Printed Name of Participant |  |  |
|  |  |  |
| Signature of Participant |  | Date |

|  |
| --- |
| **CONSENT DISCUSSION CONDUCTED BY:** |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Printed Name |  | Date Received |

|  |
| --- |
| **SIGNATURE OF LEGALLY AUTHORIZED REPRESENTATIVE** *(Optional- delete if not needed)* |

I have read the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction.

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Printed Name of Legally Authorized Representative |  |  |
|  |  |  |
| Relationship to Participant |  |  |
|  |  |  |
| Signature of Legally Authorized Representative |  | Date |

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| --- |
| **SIGNATURE OF WITNESS** *(Optional- delete if not needed))* |

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Printed Name of Witness |  |  |
|  |  |  |
| Signature of Witness |  | Date |