**Template version date: January 21, 2019**

Instructions for use of this consent form template:

* This template begins with an Invitation/Study Summary section designed to serve as the concise and focused presentation of key information. Include the following Invitation/Summary section below to comply with Common Rule requirements if the consent form(s):
  + Follows a UW-Madison Health Sciences IRBs template but is more than 10 pages; or
  + Is more than 5 pages and does not follow a UW-Madison Health Sciences IRBs template.
* On page one of this template, type in information in the header and in the footer.
* Type in appropriate names and phone numbers where indicated on final page and signature page.
* Delete this instructions section.
* Where applicable, please use the recommended section headings below.
* No extra space needs to be left on any page for the IRB approval stamp; space for such approval has already been set aside in the footer which appears at the bottom of every page.
* For studies that use more than one consent form, include the consent form type/title either in the footer, or in the heading of the consent form
* Additional elements may be required for VA research when appropriate

**STUDY SPONSOR:**

**[If the study is supported by VA or other external funds, include the heading above and identify the sponsor. If there is no study sponsor, delete this section.]**

**INVITATION/STUDY SUMMARY**

**What is this study about?**

Provide a brief, [plain language](https://plainlanguage.gov/guidelines/) description of the study’s purpose.

**What will happen during the study?**

Provide a brief, plain language description of the main *research* activities, such as investigational treatments or extra procedures that are performed for research purposes.

**How much time will I spend on the study?**

Provide a brief, clear summary of the time commitment required by the study. Both the overall length of participation and the amount of time required for study visits or other study-related activities are relevant. Do NOT detail each visit or study procedure. Use ranges of time, frequency of visits, comparisons with standard care, and similar strategies to keep this section short and easy to understand.

**Could taking part in the study help me?**

Briefly state whether subjects can reasonably expect to benefit directly from taking part in the study.

**What are the main risks of taking part in the study?**

Do NOT simply copy and paste all the common risks listed outside the Invitation/Summary section of the consent form.

*For treatment studies:* Briefly describe the risks most important to making a decision about study participation. For treatment studies, this might include side effects that are different from those associated with standard treatment. It could be those risks a clinician would consider essential to discuss with a patient.

*For non-treatment studies:* Briefly describe the risks most important to making a decision about study participation.

**How is research different from health care?**

**[Only include this section if the study involves a patient population.]**

**For treatment studies include the following language**:

When you go to a health provider for care, the provider focuses on how to help you as an individual. When you take part in a study, you are helping to answer a research question, like how safe or effective a treatment is, or what dose to use. Treatment is based on a study plan, not on you as an individual.

**For non-treatment studies include the following language**:

When you take part in a study, you are helping to answer a research question.

**More information about this study**

**WHAT IS THE PURPOSE OF THE STUDY?**

**WHAT WILL MY PARTICIPATION INVOLVE?**

**ARE THERE ANY RISKS?**

**ARE THERE ANY BENEFITS?**

## ARE THERE ANY COSTS?

Veteran-subjects, or non-Veteran subjects participating in this VA study, will not be required to pay for care received as a subject in a VA research project. Some veterans are required to pay co-payments for medical care and services provided at the VA. These co-payments requirements will continue to apply to medical care and services provided by the VA that are not part of this study.

## ARE THERE ANY ALTERNATIVES?

## WILL I RECEIVE THE RESULTS OF RESEARCH TESTS?

**[Only include this section if the study involves the analysis of biospecimens, images, or health data. Explain whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.]**

## WILL I BE PAID FOR MY PARTICIPATING IN THE STUDY?

**[If subjects are to be paid for participating in this research, include the following language as part of the description of the payment rates and method.]**

To receive payment for your participation in this study, you may be required to provide your social security number and bank account information. This information will be used by the VA to pay you for this study and will not be kept by the study team.

**WILL THERE BE COMPENSATION FOR INJURY?**

## [*WHEN PROCEDURES OCCUR ONLY AT FACILITIES UNDER MADISON VA PURVIEW INCLUDE THE LANGUAGE BELOW.*]

**Will there be compensation for injury if I am injured?**

In the event you sustain injury as a result of participation in this investigation, all necessary and appropriate care will be provided. However, the VA may not pay for the costs of treatment for injuries that result from your non-compliance with study procedures.

## [*WHEN ANY STUDY PROCEDURES OCCUR AT THE UW HOSPITAL, UW MEDICAL FOUNDATION SITES, AND/OR SITES UNDER UW-MADISON PURVIEW INCLUDE THE FOLLOWING LANGUAGE*:]

**Will there be compensation for injury if I am injured?**

In the event you sustain injury as a result of participation in this investigation, all necessary and appropriate care will be provided. However, the VA may not pay for the costs of treatment for injuries that result from your non-compliance with study procedures.

**Will UW-Madison, UW Medical Foundation or UW Hospital provide any injury compensation in addition to that provided by the VA Hospital?**

In the event that you are injured as a result of participating in this research at a UW Health facility, emergency care will be available. There is no commitment by UW-Madison, UW Medical Foundation or UW Hospital to provide any compensation for research-related injury. The VA Hospital will reimburse UW-Madison, UW Medical Foundation or UW Hospital for any charges that may result from emergency care at the UW Health facility.  You have not released UW-Madison, UW Medical Foundation or UW Hospital from liability for negligence.  Please contact the investigator, (name) at (phone number) if you are injured or for further information.

## IF I DECIDE TO START THE STUDY, CAN I CHANGE MY MIND?

**WILL INFORMATION FROM THIS STUDY GO INTO MY MEDICAL RECORD?**

**[Only include this section if the study involves a patient population. Explain in this section whether information created as the result of participation in the research study will go into the participants’ medical records.]**

**HOW WILL MY CONFIDENTIALITY BE PROTECTED?**

Your information used for this study will be kept confidential as required by law. The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you. Current VA regulations require us to keep study records indefinitely. [IF DATA, IMAGES, AND/OR SAMPLES FROM THIS RESEARCH STUDY WILL BE SHARED WITH OTHER RESEARCHERS OUTSIDE THE MADISON VA, INCLUDE LANGUAGE DESCRIBING WHAT WILL BE SHARED HERE, such as “Your [data, images, samples] will be shared with researchers at the University of Wisconsin-Madison who are working on this study with us. By signing this consent form and the HIPAA authorization form you are giving us permission to share your [data, images, samples] with these researchers.”] Your identity will not be disclosed unless you give specific consent or if required by law. There are times when we may have to show your records to other people. For example, representatives from offices and agencies that oversee research may review your records, such as UW and Madison VA research oversight offices or other federal agencies that oversee research such as the FDA, the Office for Human Subjects Protections, the VA Office of Research Oversight, or the VA Office of the Inspector General.

**[If the study is FDA-regulated include the following language in this section.]**

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.

**[If data from this study will be stored on the UW OnCore database system, in addition to your other confidentiality-related language please include the language below.]**

Information about you and your participation in this study may be entered into an electronic database at the University of Wisconsin-Madison. This database, known as OnCore, will be used to track information about this study. Information stored in OnCore may be used by OnCore data management staff or for other research activities. Only individuals with appropriate permission can look at identifiable information about you in OnCore. Data entered into OnCore will no longer be owned by the VA and will not be under VA control.

Also, with appropriate institutional permissions and confidentiality protections, we might use information [and biospecimens] that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

## COULD SAMPLES COLLECTED FROM ME BE USED FOR WHOLE GENOME SEQUENCING?

## [Only include this section if the study involves the collection or use of biospecimens. Adapt the following language for the consent document. If biospecimens are collected but will not be used for whole genome sequencing, explain this.]

## *For studies where whole genome sequencing might be possible*

## [At some point in the future], we are [may be] will look at all or large sections of your genetic code. This is often called whole genome sequencing. Genomic information relates to the structure and function of all of the genetic material in the body.

## *For studies where whole genome sequencing will definitely not occur*

We do not plan on using the biospecimens that we will collect for this research to study all or large sections of the genetic code of participants. Genomic information relates to the structure and function of all of the genetic material in the body. Looking at the entire or most of someone’s genetic code is often called whole genome sequencing.

## WHAT IF I HAVE QUESTIONS?

If you have questions or concerns about this research, please contact the VA study investigator,

(name) at (phone number) . [IF THERE ARE ADDITIONAL STUDY TEAM MEMBERS THE RESEARCH SUBJECTS CAN CONTACT, ADD THAT INFORMATION HERE, SUCH AS, “You can also contact the study coordinator, X, at X number if you have questions or concerns about the research.] For information on the rights of research subjects, please contact the VA hospital patient relations representative at (608) 280-7182. If you want to confirm this is a valid VA study, please call the VA Research Office at (608) 280-7007.

In case there are medical problems or questions, call

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| --- | --- | --- | --- | --- | --- | --- | --- |
| Name | at | Phone Number | during the day and | Name | at | Phone Number | after |

hours. If any medical problems occur in connection with this study, the VA will provide emergency care.

**AUTHORIZATION SECTION**

**I have read the information in this consent form, reviewed any questions, and I voluntarily agree to participate in this study. I have received a copy of this consent form.**

Subject’s Signature Date

Last 4 digits of Subject’s Social Security Number

DELETE SUBJECT’S REPRESENTATIVE SIGNATURE LINE FROM THE CONSENT FORM IF THE STUDY IS NOT SPECIFICALLY APPROVED FOR SURROGATE CONSENT PROCEDURES. ONLY INCLUDE IF THE STUDY IS APPROVED FOR SURROGATE CONSENT.:

:

:

Signature of Subject’s Representative\* Subject’s Representative (print)

:

Date\*

Signature of Person Obtaining Consent Date

DELETE THIS FOOTNOTE IF STUDY IS NOT SPECIFICALLY APPROVED FOR SURROGATE CONSENT PROCEDURES. ONLY INCLUDE IF THE STUDY IS APPROVED FOR SURROGATE CONSENT.: :

: \*Only required if subject is not competent.