*This template is meant to serve as a* ***guide*** *for study teams for use when requesting a Waiver of Documentation of Informed Consent. The IRB usually requires that the study team provide potential participants with the elements of informed consent in writing prior participating in the research. This can be done in the form of an information sheet that includes key, general and basic elements of informed consent provided in this template.* ***NOTE:******There may be additional elements and/or information required depending on study design/protocol. For examples and additional guidance, please refer to the VAPORHCS Informed Consent Form Template.***

*INSTRUCTIONS:*

1. Once finished with preparing the information sheet for a specific study, delete all instruction text. The information sheet should begin with the heading “WHAT AM I BEING ASKED TO DO?”
2. Any **blue text** within greater/less than symbols (< >) should be replaced with study-specific text and the symbols removed from the final information sheet. **All text in the final document should be black.**
3. **If this is a multi-site study,** the information sheet should only cover the VAPORHCS research activities (research conducted while on VA time, utilizing VA resources (e.g. equipment), or on VA property).
4. **Remove Instructions and Notes in *red italics***prior to submission to the IRB.

**WHAT AM I BEING ASKED TO DO?**

You are being asked to participate in a research study conducted by <insert name and location>. We are conducting a study to <insert main study objective>. We are asking you to take part in this research study because <insert reason>.

Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled.

# DO THE RESEARCHERS HAVE A PERSONAL, FINANCIAL OR OTHER INTEREST IN THIS STUDY?

*This subheading/element is not required if investigators* ***DO NOT*** *have a conflict of Interest.*

*If an investigator involved with this research study* ***DOES*** *have a conflict of interest in the research study, as defined in the VA Portland Health Care System Conflict of Interest in Research Form, include the following:*

<Investigator’s name> <receives payments for lecturing for and/or has an equity interest in and/or receives royalty from a patent associated with and/or serves in an executive position with> <Sponsor name>, a sponsor of this research study. This conflict has been reviewed and managed by the VAPORHCS Conflict of Interest in Research Committee.

**WHY IS THIS STUDY BEING DONE?**

We are conducting a research study to <insert short summary of study purpose(s)/aim(s)>.

**WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?**

*Briefly summarize in a bulleted list or short paragraph the study procedures, test, exams and the time commitment/duration. If questionnaires, surveys, diaries or other data collection tools will be used, state what kinds of questions are being asked, how long the tasks will take to complete, and whether subjects will be required to answer all questions.*

***NOTE:*** *Any procedures that are experimental must be specifically identified. If there are procedures being done solely for research purposes they must be identified as such and clearly distinguished from the usual care provided to subjects.*

***EXAMPLE:*** *If you decide to participate, you will be asked to have a number of tests and procedures including:*

* *Study drug daily (1 pill daily)*
* *Five blood draws*
* *CT scan every 3 months*
* *Optional cheek swab for genetic testing*

***EXAMPLE:*** *Your participation in the study will consist of <XX] visits over [XX days/weeks/months>. Visits will last up to <XX minutes/hours/days>. We may ask to follow your health through <medical record review/follow up phone calls> for up to <XX weeks/months/years>.*

*Indicate if the participants will receive any aggregate or individual study results.*

**WHAT ARE THE RISKS and POSSIBLE DISCOMFORTS of PARTICIPATION?**

*Methodically describe reasonably foreseeable risks, side effects, discomfort, and inconveniences related to the research. Identify any procedures, etc. that are usual/standard care and who will explain any risks associated with that usual care, separate from the research risks.*

***If applicable, include risks of a breach of confidentiality or an invasion of privacy****. Invasion of privacy reflects access to a person’s body or behavior without consent; confidentiality of data concerns safeguarding information that has been given voluntarily by one person to another. A breach in confidentiality may result in psychological harm to individuals (in the form of embarrassment, guilt, stress, etc.) as well as economic harm (e.g., if a social security number were used by someone to gain access to a bank account or credit card through identity theft). Specifically, consider and address the risk of breach of confidentiality or psychological trauma. Suggested language follows:*

Information that identifies you will be used in this study and shared with <insert who: e.g., such as research staff, etc.>. The research team will make every effort to protect your information. However, a breach in confidentiality and a resulting loss of privacy could result in monetary loss due to identity theft. It also could carry other risks, such as embarrassment or affecting <list applicable risks: e.g. ability to get insurance, current or future job status, plans to have a family, relations with your family, immigration status, parental rights or responsibilities, credit history or status in the community.>

***If applicable, include a statement about psychological risks,*** *such as the impact of learning results if no effective therapy exists or on plans to have children.**Suggested language follows:*

As a result of participation in this study, you may learn information <describe information that could be learned> that could be upsetting to you. If you are upset about the results learned during the course of the research study, Dr. <PI or, as applicable, Responsible Clinician name> may refer you to a counselor.

***For studies that include populations at risk of suicide, please include the following:***

If you should ever express thoughts of wishing to harm yourself or considering suicide, we may call the National Suicide Prevention Hotline and/or the Veterans Crisis Line and transfer you to that call.

***For studies involving interviews/questionnaires/Quality of Life (QOL) assessments that discuss sensitive issues*** *(any questioning that could evoke negative or troubling emotions or create uncomfortable circumstances), the risk of emotional upset must be described, and subjects must be informed that they may refuse to answer questions that upset them.* *Suggested language follows:*

Some of these questions may seem very personal or embarrassing. They may upset you. You may refuse to answer any of the questions. If the questions make you very upset, we will help you to find a counselor.

**WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?**

*Summarize any reasonably foreseeable/potential benefits of participation.*

***If applicable, describe appropriate alternative procedure(s)*** *or courses of treatment, if any, that might be advantageous to the subject.*

***NO BENEFIT EXAMPLE TEXT:*** *You will not directly benefit from taking part in this research.*

***NO BENEFIT EXAMPLE TEXT:*** *This study is not likely to help you. However, it may help the study doctors learn things that may help other people in the future.*

**WHO WILL SEE MY INFORMATION AND HOW WILL IT BE PROTECTED?**

Your information used for this study will be kept confidential as required by law. *Include description of the procedures that will be followed to ensure adequate privacy and security.*

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. Your identity will not be disclosed unless you give specific, separate consent or if required by law. All VA research records will be held in accordance with the VA records control schedule.

***Modify according to study design:***

There are times when we might have to show your records to other people. For example, someone from the Office of Human Research Protections (OHRP), the Government Accountability Office (GAO), the Office of the Inspector General (OIG), the VA Office of Research Oversight (ORO), the VAPORHCS Institutional Review Board (IRB) and Research and Development Committee (R&DC), and other study monitors may look at or copy portions of records that identify you.

***Required for all studies using identifiers for any purpose:***

In the future, identifiers may be removed, and de-identified <information and/or biospecimens> about you used for future research studies (not part of this study) without additional informed consent obtained from you. This means the people working on future research studies will not be able to identify who you are.

***If video/audio tapes or photographs are being used*** *for research purposes, include the statements below and indicate whether or not subjects will be identifiable, or how identity will be concealed. Indicate whether or not photographs, videos, and/or audio recordings will be disclosed outside the VA and, if they will be, include to whom they will be disclosed (as applicable).* ***NOTE:*** *VA Form 10-3203 Consent Video or Audio Recordings by VA (available at: (*[*http://www.va.gov/vaforms/medical/pdf/vha-10-3203-fill.pdf*](http://www.va.gov/vaforms/medical/pdf/vha-10-3203-fill.pdf)*) must be signed by the research participant, or consent for the photograph(s) or recording(s) must be documented using a method approved by the VAPORHCS Information Security and Privacy (ISAP) group. Please contact the VAPORHCS Privacy Officer and/or IRB for guidance if you would like to use a documentation method other than VA Form 10-3203.*

***Modify depending on Privacy Officer approved method and/or study use of photograph, digital image and/or audio recording.***

The <photograph, digital image and/or audio recording> will be produced while *<describe the activity or situation>* for the purpose(s) of <describe how the image and/or recording will be used>. You will be asked to provide your verbal consent for the use of the <photograph, digital image and/or audio recording>. By providing your verbal consent you authorize the use of the *< photograph(s), digital image(s), and/or video or audio recording(s)>* for research purposes.All research-related <video/audio tapes or photographs> will be held in accordance with the VA records control schedule.

***Required paragraph for studies involving interviews, questionnaires, surveys, or other procedures during which such information may be learned.***

**Mandatory reporting of suspected child, elder, or vulnerable adult abuse.** Under Oregon Law, suspected child, elder or vulnerable adult abuse must be reported to appropriate authorities.

**WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?**

***If participants will be compensated for participation,*** *or for expenses associated with participation, indicate*

*how the subject will be compensated, the schedule for receipt of compensation, the amount of compensation, and how the amount will be prorated if the subject withdraws before completing the study.*

***Modify the following language according to study design/protocol.***

You will be paid $<amount> for each <indicate study related procedure - e.g. blood draw/session> that you complete. You will receive the <cash, check, etc.> payment at the end of each <indicate study related procedure >. If you drop out of the study before completing all the <indicate study related procedures >, you will be paid for the <indicate study related procedure> that you completed. If you complete all of the scheduled <indicate study related procedure >, you will have received a total of $<amount>.

***NOTE:*** *If applicable, delineate travel reimbursement from compensation for participation payment(s) and clarify that subjects will not receive dual travel reimbursement for a given day (e.g. beneficiary travel with qualifying medical appointment and travel reimbursement for research visit on same day).*

***If study will use Electronic Funds Transfer (EFT) or checks for participant payment(s)*** ***(Remove references to any form of payment not used in this study.):***

Studies that include subject reimbursement using a check or electronic funds transfer (EFT) will use your Social Security Number. To receive payment by EFT, you will also be required to provide banking information for payment purposes. Your banking information will not be used for research purposes. An Internal Revenue Service (IRS) Form 1099 may be generated, which will use your Social Security Number. This payment is considered taxable income. If you owe money to the government, this payment may be garnished to satisfy the debt.

**WHO CAN I TALK TO ABOUT THIS STUDY?**

To speak to someone about the research, call <name> at <phone number>. *If you give the name and number of the PI, be sure someone will always be available to answer at that number. Consider whether a research coordinator would be a better contact, or give more than one contact.*

If you become sick or injured or if you feel your privacy or confidentiality may have been violated (e.g., someone without authorization has received personal information about you), call <name of PI or responsible clinician> at <phone number>.

To speak with someone not connected with this research study about your rights, discuss problems, concerns and questions, obtain information and/or offer input, please call the VA Portland Health Care System Research Office at (503) 273-5125, or the VAPORHCS Privacy Officer at (503) 273-5037.

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to your non-compliance with study procedures. Additional compensation, beyond paying for treatment, has not been set aside.