

**INSTRUCTIONS: Consent & Authorization Form for Non-Medical Intervention, Education, Health Promotion Research Protocols, and for Subjects with Low Literacy**

1. *Instructions in italics are provided throughout the sample form. These instructions are for your information. Please delete all instructions before submitting to the Institutional Review Board (IRB).*
2. *Consent forms must be written in language suitable for subjects who read at the eighth-grade level!*
  - *For guidance on simplifying the language of consent forms, visit: <http://www.ohsu.edu/research/rda/irb/docs/policies/readtips.pdf>.*
3. *Follow these standards when writing the consent form:*
  - **Items in [square brackets] indicate action from you such as making a choice or inserting study relevant information.**
  - **Write out terms before using the acronym.**
  - **Do not use abbreviations.**
  - **Use the term subject or participant, not patient.**
  - **Use the term investigator or study doctor, not doctor or physician.**
  - **Insert page numbers.**



**Oregon Health & Science University**  
Consent & Authorization Form

IRB#: \_\_\_\_\_

Protocol Approval Date: \_\_\_\_\_

*[Ensure the initial/annual approval date is inserted into the stamped approved consent form from the IRB]*

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**OREGON HEALTH & SCIENCE UNIVERSITY**  
Consent & Authorization Form

**TITLE:** *Title of the study. Use the same title as that on the Initial Review Questionnaire (IRQ).*

**PRINCIPAL INVESTIGATOR:** [list name and degree(s)] (503) 494-####

**CO-INVESTIGATORS:** [list name and degree(s)] (503) 494-####  
[list name and degree(s)] (503) 494-####

*The Principal Investigator (PI) must be listed on the consent form and must be the same PI listed on the IRQ. It is recommended that no more than 5 additional personnel be listed, but others may be listed if required by the sponsor. The phone number(s) should match the phone number(s) on the HIPAA Research Authorization (HRA) and IRQ.*

**SPONSOR:** *List the sponsor's name here, and then refer to the sponsor as "the sponsor" in the text.*

This form contains important information about the study in which you are being invited to participate. Please read the form carefully, ask questions of the investigators or others who are obtaining your consent to participate in the study, and take time to think about your participation. You may want to discuss the study with your family or friends before agreeing to be in the study.

**What is the purpose of this study?**

*Describe the purpose of the study in language suitable for subjects who read at the 8<sup>th</sup> grade level.*

**What is required to participate in this study?**

To qualify for this study, you must meet the following criteria:

1. *List*
2. *List*
3. *etc.*

**What can I expect as a study participant?**

*State what subject will do/what will be done with subject over the course of the study such as, “We will interview you X times; we will ask you to complete a questionnaire X times; someone will call you on the telephone, etc.”.*

*State how long the study will last. Sample language (modify as appropriate):* This study requires 7 visits to the clinic and will take 8 weeks to complete.

**At the end of this section, you must insert the following statement:** If you have any questions regarding this study now or in the future, contact [PI Name (503) 494-####] [or other members of the study team at (503) ###-####]. *(the PI phone number should match the first page of this consent form and the IRQ).*

**What effect will this study have on my care?**

*State if the study participation will change or alter the subject’s standard care in any way. If there will be no effect on standard care, state this. Sample language (modify as appropriate):* Being in this study will not affect any care that you might receive at OHSU.

**How will my privacy be protected?**

We will protect your privacy in the following ways:

1. Your name or other protected information will not be used. Instead, we will identify you by *[state if information is coded]*.

2. Only *[state who will have access to identified information]* will be able to access your information.
3. *[State any additional protections]*.

The specific health information we will collect from you will be limited to *[state what health information is collected, such as, "your responses to questions in a questionnaire and/or interview with the investigator"]*. The purposes of our use and disclosure of this health information are described in the **Purpose** section of this Consent & Authorization Form.

The persons who are authorized to use and/or disclose your health information are all of the investigators who are listed on page one of this Research Consent Form and the OHSU Institutional Review Board.

The persons who are authorized to receive this information are *[name the sponsor of the study, if there is one]* and the Office for Human Research Protections *[name the federal or other governmental agencies that may inspect the data or review the study]* as required for their research oversight and public health reporting in connection with this research study.

This authorization will expire and we will no longer keep protected health information that we collect from you in this study *[Enter a date or "study is completed," "indefinitely," or similar language]*.

#### **What are the possible risks of participating in this study?**

Although we have made every effort to protect your identity, there is a minimal risk of loss of confidentiality. *[Add other risks if necessary]*.

#### **What are the possible benefits of participating in the study?**

***Unless direct benefits to the subject are assured, use the following language:*** You may or may not personally benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

***When the subject will not benefit, but is participating from idealistic motives, use the following language:*** You will not benefit from being in this study. However, by serving as a subject, you may help us learn how to benefit patients in the future.

#### **Will it cost anything to participate?**

***State if subjects will need to pay anything to participate in the study. If subjects will be traveling to OHSU, state if travel expenses and/or parking will be reimbursed. State if subjects will be paid for participation, how much, and how pro-rated if the subject discontinues prematurely.***

#### **What if I am harmed or injured in this study?**

(NOTE: You may not modify the language in the liability section without seeking the permission of the ORIO.)

To determine the correct liability language for the study, please access the liability language chart at [http://www.ohsu.edu/research/rda/irb/liability\\_language.shtml](http://www.ohsu.edu/research/rda/irb/liability_language.shtml).

### **What are my rights as a participant?**

**1. State:** If you have any questions regarding your rights as a research subject, you may contact the OHSU Research Integrity Office at (503) 494-7887.

**2. State:** You do not have to join this or any research study. If you do join, and later change your mind, you may quit at any time. If you refuse to join or withdraw early from the study, there will be no penalty or loss of any benefits to which you are otherwise entitled.

**3. State:** You have the right to revoke this authorization and can withdraw your permission for us to use your information for this research by sending a written request to the Principal Investigator listed on page one of this form. If you do send a letter to the Principal Investigator, the use and disclosure of your protected health information will stop as of the date he/she receives your request. However, the Principal Investigator is allowed to use information collected before the date of the letter or collected in good faith before your letter arrives. Revoking this authorization will not affect your health care or your relationship with OHSU. ***[PIs: If you intend to anonymize/de-identify the information collected, please state that and advise subjects that it will be impossible to remove their information from the study because you will have no way to link the information to a specific subject]***

**4. If there is any intent to disclose or otherwise send research subject data outside of OHSU, state:** The information about you that is used or disclosed in this study may be re-disclosed and no longer protected under federal law. However, federal or state law may restrict re-disclosure of HIV/AIDS information, mental health information, genetic information and drug/alcohol diagnosis, treatment, or referral information. OHSU tries to protect against re-disclosure without your permission by being very careful in releasing your information.

**5. State:** If the researchers publish the results of this research, they will do so in a way that does not identify you unless you allow this in writing.

**6. If the investigator is also the patient's health care provider, state:** Your health care provider may be [one of] the investigator[s] of this research study, and as an investigator is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your care from another doctor who is in no way involved in this project. You do not have to be in any research study offered by your physician.

**7. Clarify under what circumstances the subject may be removed from the study prior to study conclusion. State:** You may be removed from the study if [choose as appropriate:  
*if the investigator stops the study.*

if the sponsor stops the study.  
if you become pregnant.  
if you develop serious side effects.  
if your disease gets worse.  
if you fail to respond to treatment.  
if you do not follow instructions.]

**8. Where applicable, include a statement that subject will be informed of new findings that may affect the subject or his/her wish to continue participation.**

**9. Indicate what will happen if a subject chooses to withdraw.** For example, list the visits and/or procedures the subject will be requested to complete.

**10. For studies recruiting OHSU students or employees as subjects, please include the following language:** The participation of OHSU students or employees in OHSU research is completely voluntary and you are free to choose not to serve as a research subject in this protocol for any reason. If you do elect to participate in this study, you may withdraw from the study at any time without affecting your relationship with OHSU, the investigator, the investigator's department, or your grade in any course.

**11. State:** To participate in this study, you must read and sign this consent and authorization form. If you withdraw your authorization for us to use and disclose your information as described above, you will be withdrawn from the study.

**12. Include a statement that the person signing the consent form will be given a copy:** We will give you a copy of this form. [or] We will give you a copy of this signed form.

**13. A Child Assent Form should be attached to the consent form, if the study subject is a child between 7 and 17.**

## **SIGNATURES:**

1. **The last paragraph should be:** Your signature below indicates that you have read this entire form and that you agree to be in this study.

LEAVE 4 INCHES BETWEEN THE LAST PARAGRAPH OF THIS PAGE AND THE  
SIGNATURE LINES.  
APPROVAL/EXPIRATION STAMP WILL GO HERE.

**Include signature and date for the subject.**

**Include signature, print name, and date lines for the person obtaining consent.**

**When applicable:**

- a. *Lines for parent, guardian, or legally authorized representative should be included (for example, children, cognitively impaired,) as well as a line for the description of their relationship to subject.*
- b. *Signature lines for witnesses are not required by the OHSU IRB, but may be included if required by the study sponsor.*