

## **INSTRUCTIONS: Consent and Authorization Form**

This sample form combines both consent and authorization by including language from the HIPAA Research Authorization (HRA) form within the section entitled “Confidentiality and Privacy of your Protected Health Information.” Language designated in the template as required may not be modified. Suggested language in the template must also be used unless the language is not consistent with the study. Consent forms containing modifications to required and suggested language will be returned to the submitter without review unless the modifications have been approved by the IRB prior to submission. **If the study intends to store or bank blood or tissue for unspecified future research, you may not use the combined consent and authorization.**

**Note:** Please ensure you are using the correct sample and addendums for your study.

- a. If you would rather not use a combined form, you can find a sample consent form at: [http://www.ohsu.edu/research/rda/irb/docs/sample\\_forms/samplecf.doc](http://www.ohsu.edu/research/rda/irb/docs/sample_forms/samplecf.doc) and a HIPAA Research Authorization (HRA) form at: <http://www.ohsu.edu/cc/hipaa/forms.shtml>.
    - For more information on HIPAA regulations, please visit: <http://www.ohsu.edu/cc/hipaa/hipaarpp.shtml>
  - b. If the study includes **genetic analyses** of blood or tissue, or if the study requests permission to **store blood or tissue for future research**, use the genetic consent form sample instead, available at: [http://www.ohsu.edu/research/rda/irb/docs/sample\\_forms/gene.doc](http://www.ohsu.edu/research/rda/irb/docs/sample_forms/gene.doc).
    - For more information on what qualifies as genetic research, please visit: <http://www.ohsu.edu/research/rda/irb/genetic.shtml>.
  - c. Consent and authorization forms for studies involving **OHSU clinical services** should include a barcode in the margin and sections to allow entry of the subject's name, MRN, and birth date.
    - A sample consent form with a barcode that combines both consent and authorization is available at: [http://www.ohsu.edu/research/rda/irb/docs/sample\\_forms/samplecf\\_authorization\\_bar.doc](http://www.ohsu.edu/research/rda/irb/docs/sample_forms/samplecf_authorization_bar.doc).
    - A sample consent form with a barcode is available at: [http://www.ohsu.edu/research/rda/irb/docs/sample\\_forms/samplecf\\_bar.doc](http://www.ohsu.edu/research/rda/irb/docs/sample_forms/samplecf_bar.doc).
    - The HRA with a barcode is available at: <http://www.ohsu.edu/cc/hipaa/forms.shtml>.
  - d. If the study collects **media** (photographs, video tapes, or audio recordings) from subjects and the media will be displayed in a public setting such as teaching, advertisement, and publication, please also prepare a Media Consent Form available at: [http://www.ohsu.edu/research/rda/irb/docs/sample\\_forms/media.doc](http://www.ohsu.edu/research/rda/irb/docs/sample_forms/media.doc).
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.**
    - a. For guidance on simplifying the language of consent forms, visit: <http://www.ohsu.edu/research/rda/irb/docs/policies/readtips.pdf>.
    - b. For a glossary of lay equivalence of medical terms, visit: [http://www.northshorelij.com/workfiles/irb\\_glossay\\_body.doc](http://www.northshorelij.com/workfiles/irb_glossay_body.doc)

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.**
  - **If your protocol involves a drug, use the generic name (not the trade name) of the drug once, then refer to the drug as “study drug” throughout. However, this may not work well if you are using more than one drug. In these cases, it may be allowable to use the generic names of the drugs.**
  - **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 and Authorization Form**

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

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

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

**OREGON HEALTH & SCIENCE UNIVERSITY  
Consent and 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-####  
[list name and degree(s)] (503) 494-####  
[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.*

**SUPPORTED BY:** *Use this heading instead of the sponsor heading to name the entity providing financial support only such as a free study drug.*

**CONFLICT OF INTEREST:** *All potential conflicts of interest in research (CoIR) must be disclosed and evaluated by the COI committee. After evaluation, the COI committee may require specific*

language to be inserted into the consent form. If directed, place the language here. For more information on CoIR, visit: <http://www.ohsu.edu/research/rda/coir/requirements.shtml>.

**PURPOSE:**

1. **If the study includes both children and adults and all procedures are identical for both children and adults, state:** “You” means you or your child in this consent form. (For other studies involving children, address the consent form to the parent referring to children as “your child.”)
2. **Include and complete the following sentences:** You have been invited to be in this research study because \_\_\_\_\_. (For example, “you have asthma.”) The purpose of this study is to \_\_\_\_\_. (For example, “learn about a new drug that may help treat asthma.”)
3. **If applicable, specify that an investigational (experimental) device, procedure, or drug is to be used. Sample language (modify to fit your study):** Right now, this drug is not approved for use for asthma in the United States because we do not know enough about it.
4. **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.
5. **Indicate how many subjects will be enrolled into the experiment both at OHSU and, where applicable, for the entire study.**

**PROCEDURES:**

1. **Describe succinctly and in chronological order those procedures that are part of the research. It is not necessary to describe procedures that subjects would be receiving as routine care even if they did not participate in the study.**

**State approximately how much time the visits and procedures will require. If studies are complex, use an uncomplicated table showing what procedures will occur at each study visit. Simplify the procedures and list them from the subject’s perspective. In most cases, tables provided by the sponsor in the study protocol are too complex to be of help to most subjects. See example:**

**Introduce your table with a heading:**

	Visit 1 Day 1	Visit 2 Day 14	Visit 3 Month 3	Visit 4 Month 6	Visit 5 Month 12
Screening tests and medical history	X				
Blood draw (1 tablespoon)	X	X	X	X	X
Chest x-ray	X			X	X
Quality of Life Questionnaire	X			X	X

Total time	4 hours	30 minutes	30 minutes	3 hours	3 hours
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2. **If blood is to be drawn, indicate the amount in lay terminology only (5cc = 1 teaspoon, 15cc = 1 tablespoon)**
  
3. **If radiation is part of the experimental study, Radiation Safety Committee review of your protocol is required. For more information on the Radiation Safety Committee, visit the web at: [http://ozone.ohsu.edu/ehrs/mh/pages/rad/rad\\_comm.shtml](http://ozone.ohsu.edu/ehrs/mh/pages/rad/rad_comm.shtml) or contact the Radiation Safety Officer (4-7795; francoj@ohsu.edu) for advice and documents. Please note that studies using DEXA scans for research purposes also need to be submitted to Radiation Safety for review.**
  
4. **If there will be a placebo arm in the study, please make this clear and explain what a placebo is. Sample language (modify as appropriate):** A placebo is a [pill, solution, cream, liquid] that looks like the study drug but has no real medicine in it.
  
5. **Indicate how subjects are assigned to different treatments or conditions. Sample language (modify as appropriate):** This is a randomized study. Neither you nor the investigator can choose whether you get the [study drug] or the placebo. [insert proportion such as one-third] of subjects in this study will get the placebo.
  
6. **Indicate whether subjects or investigators will know what treatment subjects are receiving single/double-blind. Sample language (modify as appropriate):** You and the investigators will not know which pill [or dose] you are taking. The study is done this way because knowing whether you are getting the study drug can change the results of the study. If you start having serious side effects from the study drug, the investigators can find out what you are taking in order to help you. Please ask the investigator if you have any questions at all about this kind of study.
  
7. **If questionnaires, surveys, diaries, or other data collection materials are being used, mention what kinds of questions will be asked and how long the tasks will take to complete, and submit a copy of each along with your consent form.**
  
8. **If the subject's medical records will be reviewed, describe the information to be collected.**
  
9. **At the end of the procedures 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, the IRQ, and the HRA).

### **RISKS AND DISCOMFORTS:**

1. **Describe reasonably foreseeable risks, side effects, discomforts, and inconveniences. List the risks in order of their importance. For example, if the study involves a drug with life-threatening side effects, these should be listed first. When listing other side effects, arrange risks from most to least likely. Avoid listing very serious side effects between two mild side effects and vice versa.**

2. **For studies involving investigational drugs or devices, state:** You may have some side effects we do not expect because we are still learning about \_\_\_\_\_.

3. **Indicate risk of inducing malignancy, if relevant.**

4. **Use standard wording where applicable:**

**For blood draw:** We will draw blood from [*location on the body*]. You may feel some pain when your blood is drawn. There is a small chance the needle will cause bleeding, a bruise, or an infection.

**For MRI:** The magnetic resonance imaging (MRI) machine is a powerful magnet, this magnet may cause any metal in your body to move. If you know of any metal in your body, you will need to tell the investigator right away. Otherwise, there are no known risks of MRI. Some individuals with claustrophobia (fear of closed spaces) may find the MRI equipment too confining. In that case, you can request to be removed from the scanner and this will be done immediately. The MRI scanner makes a loud beeping sound. You may be asked to wear protective earplugs during scanning. The dye that is injected [*location of dye injected*] for the scan is well tolerated. Some people feel dizzy or queasy or get a headache with it or notice a cold feeling near the injection site. There is a rare chance of having an allergic reaction to the dye that very rarely can be serious and life threatening.

**For x-rays, DEXA scans, and nuclear medicine procedures, including PET scans:** In this study, you will be exposed to radiation during the [*name of the procedure*]. While we cannot be sure any dose of radiation is entirely safe, the amount you will be exposed to in this study is not known to cause health problems.

**For CT scans:** In this study, you will be exposed to radiation during the CT scan. Although the amount to which you will be exposed is higher than from a typical x-ray, the risk of harmful effects from a single exam is very small.

**For fluoroscopy:** In this study you will be exposed to radiation during the fluoroscopy for [*name of the procedure*]. There is a small chance this will cause you to lose your hair. There is a rare chance that your skin may turn red or be damaged. If your skin damage is severe, you may need medical treatment.

**For indwelling catheter:** You will have a catheter (tube) in your vein for more than 24 hours. You may get an infection where the tube is placed. This would cause swelling, redness, and pain. You may bleed or get a bruise. There is a small chance your blood stream or heart valves might get a serious infection. You may get a blood clot that could go to your lungs. These problems are very rare. If you have these problems, you will need hospital care. Your catheter will be in place for [*state time*].

**For endoscopy:** The endoscope may make you gag. It may make you feel queasy or give you a sore throat. There is a small chance your esophagus, stomach, or small intestine may bleed. You may get an infection. You may feel drowsy after taking the drug that relaxes you before the endoscopy. You should not drive a car or operate machinery for 24 hours afterward. . Once in a great while, an endoscopy makes a hole in someone's esophagus or stomach. This happens about 1 time in every 5,000 endoscopies. If this happens to you, you may need to have surgery to repair the hole.

**For bone marrow biopsy:** Bone marrow biopsy means taking some cells from inside your bones. To do this, we will numb an area of your skin (usually near your hip) with a shot. The shot may cause a little pain. Some people (fewer than 1 in 10,000) are allergic to the shot you will get to numb the area. Then we will insert a long needle into your bone to get the cells. Some people have moderate to severe pain when the bone marrow cells are drawn in through the long needle. Your hip may hurt for about 3-6 days. There is a small chance you will get a bruise or an infection where the needle will be inserted. You may bleed or have a scar. Your skin may itch. These problems are rare.

**For skin biopsy:** In this study, we will remove a small piece of skin from [location]. This is called a skin biopsy. To do this we will give you a shot to numb the area. The shot may cause a little pain. Some people (fewer than 1 in 10,000) are allergic to the shot you will get to numb the area where the skin is taken. Heavy bleeding from a skin biopsy is rare. Skin biopsies cause infections about 10% of the time. A small scar will form at the biopsy site. The scar is usually much smaller than the original biopsy.

**For protocols involving surgery that is NOT investigational:** You are invited to be in this research study because you are scheduled to have [name procedure]. You have already consented to that procedure. That procedure is not experimental and is not part of this study. The risks of [name procedure] have already been discussed with you and a copy of that consent form is attached to this research consent form. **NOTE: If you choose to include this statement, you must provide a description of the significant risks of the procedure in a separate clinical consent form and attach a copy of the clinical consent form to the research consent form. If you choose not to use this statement, you must provide the risks of the procedure in this consent form and state clearly that these risks are the same as they would be if the subject was not part of the research.**

**For “statin” drugs:** Researchers think drugs like [indicate drug name, such as atorvastatin, fluvastatin, simvastatin, pravastatin, lovastatin, etcetera] might cause destruction of muscle cells. The medical term is called rhabdomyolysis. This sometimes causes pain, and may cause kidney failure. This can be fatal. If you start to have any muscle pain, pain in the calves or lower back, weakness, tenderness, fever, dark urine, nausea or vomiting you should call Dr. [Name] at [list the telephone number that is available 24-hours a day] immediately.

**For COX-2 inhibitors or similar compounds:** Some researchers believe COX-2 inhibitor type drugs might increase the risk of heart attack, stroke, chest pain (angina), blood clots, and death. We are not sure this is true but we want to be careful. To help keep you safe in this study, we will closely watch you for these side effects by [describe monitoring plan here].

**For pregnancy/risk to fetus (For Women). Choose only one of the following statements for women:**

**1. One method of birth control required for study:**

If you are nursing an infant or you are pregnant now, you must not be in the study because we do not know how this [drug, treatment, procedure] could affect a fetus. If you are sexually active and are at risk of getting pregnant, you and your male partner(s) must use a method of birth control that works well, like birth control pills, Depo-Provera, Norplant, an IUD, a diaphragm or condom with spermicide, or abstinence. You will have to do this the whole time you are in this study. If you become pregnant during the research study, please tell the investigator and your doctor immediately.

**2. Two methods of birth control required for study:**

If you are nursing an infant or you are pregnant now, you must not be in the study because we do not know how this [*drug, treatment, procedure*] could affect a fetus. If you are sexually active and are at risk of getting pregnant, you and your male partner(s) must use two methods of birth control that work well, like birth control pills, Depo-Provera, Norplant, an IUD, a diaphragm or condom with spermicide, or abstinence. You will have to do this the whole time you are in this study. If you become pregnant during the research study, please tell the investigator and your doctor immediately.

***For pregnancy/risk to fetus (For Men):*** If you are a sexually active male and at risk of causing a pregnancy, you must be sure that your female partner(s) are using a method of birth control that works well, like birth control pills, Depo-Provera, Norplant, an IUD, or a diaphragm with spermicide, or you must use a condom with spermicide during sexual intercourse, or abstinence. You must do this the whole time you are in this study. A vasectomy [*is/is not*] an acceptable method of birth control for this study. If a sexual partner becomes pregnant during the research study, please tell the investigator and ask your partner to tell her doctor immediately.

***For studies that enroll identified HIV positive subjects:*** As an HIV positive person you can give the HIV virus to your sexual partner(s) even if your viral load is very low or non-detectable. You must be sure that your sexual partner(s) knows your status. If you use a condom or female condom during intercourse, you will help reduce the risk of giving your partner HIV. Using a spermicide like nonoxynol 9 may increase the risk of giving HIV to your partner. The investigator will discuss with you ways to minimize this risk.

***For potential drug interactions:*** *Whenever a study involves the administration of medications that may interact with several other medications, the following language must be included (modify as appropriate):* There are several drugs (prescription and non-prescription) that may cause problems when taken with the study drug. The investigator will carefully review all of the drugs you are taking before giving you the study drug. If any other health care provider prescribes any new drug(s) for you while you are in this study, please tell the investigator before you take the new drug. You could also have that provider talk to the investigator before prescribing the new drug. Do not take any new over-the-counter drugs while you are in this study unless you first check with the investigator.

***For studies involving interviews/questionnaires/QOL assessments that discuss sensitive issues that may cause emotional upset, such as grieving:*** *The risk of emotional upset must be described, and subjects must be informed that they may refuse to answer questions that upset them. Sample language (modify as appropriate):* Some of these questions may seem very personal or embarrassing. They may upset you. You may refuse to answer any of the questions that you do not wish to answer. If the questions make you very upset, we will help you to find a counselor. ***NOTE: This statement is not necessary if you are discussing routine matters that do not cause emotional upset.***

## **BENEFITS:**

***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.

**ALTERNATIVES:**

**State:** You may choose not to be in this study. [*Describe alternative non-research procedures or treatments available, if any, which might be advantageous to the subject. Avoid stating or implying that there are no alternatives. If applicable, indicate that subjects need not participate in the research study to receive (the same) treatment for their condition.*]

**CONFIDENTIALITY AND PRIVACY OF YOUR PROTECTED HEALTH INFORMATION:**

(NOTE: The language in this section is required and you may not modify the language without seeking the permission of the ORIO.)

**State:** We will not use your name or your identity for publication or publicity purposes.

**If no data will be created during the course of this research study, you may detail the health information, location and purpose in a paragraph rather than tabular format. For example:** We will collect your complete existing health record at OHSU. This information will be used to learn more about the costs of treating your type of **(state the disease or condition)**.

**If data will be generated and collected solely for research purposes, you must name the specific health information and the purpose of each use/disclosure. This may be done in a table or in a paragraph format. Suggested language:** If you sign this form, you are agreeing that OHSU may use and disclose protected health information collected and created in this research study. The specific health information and purpose of each use and disclosure are described in the **(table or paragraph)** below:

**If you choose to present this information in a table, use the formatting of the table below. Health information types and purpose categories that are not relevant may be deleted from the table.**

Health Information (Check as applicable)	Purpose(s) (Enter corresponding letter(s) from Purpose Categories)
<input type="checkbox"/> Your complete existing health record ** <input type="checkbox"/> Limited information from your existing health record** (specify): _____ _____	_____ _____
<p>** If we are requesting existing health records that are located outside of OHSU, you will need to complete an additional authorization to release these records to OHSU.</p>	
<p><b>THE FOLLOWING CHECKED ITEM(S) WILL BE GENERATED/COLLECTED DURING THE COURSE OF THIS STUDY:</b></p>	

- History and physical examinations \_\_\_\_\_
- Reports:  Laboratory  Operative  Discharge  Progress \_\_\_\_\_
- Photographs, videotapes, or digital or other images \_\_\_\_\_
- Diagnostic Images/X-ray/MRI/CT \_\_\_\_\_
- Bioelectric Output (e.g., EEG, EKG) \_\_\_\_\_
- Questionnaires, interview results, focus group survey, psychology survey, behavioral performance tests (e.g., memory & attention) \_\_\_\_\_
- Tissue and/or blood specimens \_\_\_\_\_
- Other: \_\_\_\_\_

**Purpose Categories**

- a. To learn more about the condition/disease being studied
- b. To facilitate treatment, payment, and operations related to the study
- c. To comply with federal or other governmental agency regulations
- d. For teaching purposes
- e. Other \_\_\_\_\_

The persons who are authorized to use and disclose this information are: ***[List as many as are appropriate: All investigators listed on page one of this Consent and Authorization Form, others at OHSU who are participating in the conduct of this research protocol, the OHSU Institutional Review Board, Others (must specify)].***

The persons who are authorized to receive this information are: ***[List as many as are appropriate: the sponsor of this study, federal or other governmental agencies as required for their research oversight and public health reporting in connection with this research study (OHRP, FDA, other), Others (must specify)].***

We may continue to use and disclose protected health information that we collect from you in this study: ***[choose one from the following list: HIPAA Research Authorization expiration date (provide specific date), the study is completed, indefinitely, indicate any other].***

While this study is still in progress, you may not be given access to medical information about you that is related to the study. After the study is completed and the results have been analyzed, you will be permitted access to any medical information collected about you in the study.

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 the research consent 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 and disclose information collected before the date of the letter or collected in good faith before your letter arrives. If you withdraw any tissue or blood samples that were collected from you, they either will be destroyed or stored without any information that identifies you. Revoking this authorization will not affect your health care or your relationship with OHSU.

The information about you that is used or disclosed in this study may be re-disclosed and no longer protected under federal law.

If the information to be used or disclosed contains any of the types of records or information listed just below, additional laws relating to use and disclosures of the information may apply. You understand and agree that this information will be used and disclosed only if you place your **INITIALS** in the applicable space next to the type of information.

**[Investigators all items you intend to collect information on must be included; irrelevant fields may be 1) deleted - or - 2) included with N/A typed in the field. The above statement and four types of information below may be deleted if none of the information is collected.]**

- \_\_\_\_\_ Acquired immunodeficiency syndrome (AIDS) or human immunodeficiency virus (HIV) infection information
- \_\_\_\_\_ Drug/alcohol diagnosis, treatment, or referral information
- \_\_\_\_\_ Mental or behavioral health or psychiatric care
- \_\_\_\_\_ Genetic testing information

**For studies involving interviews, questionnaires, surveys, or other procedures during which such information may be learned, state:** Under Oregon Law, suspected child or elder abuse must be reported to appropriate authorities.

#### **COSTS:**

1. **If all costs are met by subject, use following language (modify as appropriate):** You or your insurance company will be responsible to pay for all charges for [hospitalization, drugs and their administration, operations, laboratory tests, imaging studies, physician fees, the reasonable and necessary cost of treatment for any unexpected complications, insurance co-payments and any other applicable costs].
2. **When the costs to a subject for an experimental procedure are expected to be high, an estimate of that cost should be given and insurance preauthorization is highly recommended.**
3. **When costs are shared, specify what costs will be covered by the sponsoring agency. Use the following language (modify as appropriate):** Some of the procedures [devices, tests, drugs] in this study are part of the regular treatment for your condition. These would be performed [given to you] even if you were not in this study. The costs for these procedures [devices, tests, drugs] will be billed to your insurance. If you are uninsured, you will be billed for them. You will be responsible for any costs your insurance does not cover. You will not be responsible for the procedures [devices, tests, drugs] that are experimental.
4. **If subjects are compensated for expenses associated with participation, indicate how, the amount, and how the amount will be prorated if the subject withdraws before completing the study.**
5. **If there are no costs to the subjects, state that explicitly.**

**LIABILITY:** (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).

## **PARTICIPATION:**

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. **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.
4. **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.]
5. **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.**
6. **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.
7. **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.
8. **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.
9. **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.***

***Consent regulations for experimental drugs and devices require that consent forms be dated at the time they are signed by the subject or subject's authorized representative [21 CFR 50.27].***

***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.***