

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

Protocol Approval Date: (current approval date)

**FOR INITIAL OR ANNUAL REVIEW, PLEASE LEAVE THE "APPROVED:" DATE BLANK AS THIS SHOULD BE COMPLETED MANUALLY AFTER YOU HAVE RECEIVED THE STAMPED APPROVED CONSENT FORM FROM THE IRB.**

**OREGON HEALTH & SCIENCE UNIVERSITY  
Genetic Consent Form Sample**

**TITLE:** *Name of the study. Use the same title as that on the IRQ.*

**PRINCIPAL INVESTIGATOR:** ..... MD (503) 494-####

**CO-INVESTIGATOR(S):** ..... (503) 494-####  
..... (503) 494-####  
..... (503) 494-####

*Investigators should be same as those listed on the IRQ.*

**SPONSOR:** *Give the name of the sponsor once here, and then refer to the sponsor as "the sponsor" in the remainder of the document.*

**PURPOSE:**

1. *Inform the subject that a sample of blood or tissue will be used for genetic research and describe the intended goal of the research protocol.*

*Suggested wording (use all that apply):*

You have been invited to participate in this research study because you have (*fill in the name of the disorder*).

The purpose of the study is to understand the inheritance of (*disorder*). If a gene or genes that cause (*disorder*) can be found, the diagnosis and treatment of (*disorder*) may be improved.

Genes are the units of DNA--the chemical structure carrying your genetic information--that determine many human characteristics such as the color of your eyes, your height, and whether you are male or female.

We are (*also*) asking you to provide blood/tissue samples for a blood/tissue bank.

The blood/tissue samples provided by you will be analyzed in the laboratory to determine whether there are differences in the genes of people with and without (*disorder*).

2. *Inform the subject how long samples will be used/stored. If samples are to be stored for potential future use in other experiments, subjects must be informed of this and should be given options (see **SIGNATURES**).*

*Suggested wording:*

Your blood/tissue samples will be stored only for this research, which is expected to last for (*duration*), and then the blood/tissue samples will be destroyed.

or

Your blood/tissue samples will be stored for (*duration; if intent is to store indefinitely, make this clear*).

### **PROCEDURES:**

1. *Describe succinctly and in chronological order only those procedures that are part of the research. State approximately how much time will be required for clinic visits and procedures.*
2. *If blood is to be drawn, indicate the amount in lay terminology (4cc = teaspoon, 15cc = tablespoon, etc.)*
3. *If there is any possibility that other investigators will be given access to samples or genetic information for research in the future, the subjects must be informed of and specifically consent to this possibility.*

*Suggested wording:*

In the future, [*samples of your blood/tissue/genetic information/medical information*] may be given to researchers as part of the search for a genetic cause of (*disorder*) [*or for other research purposes*]. The samples will be labeled as described in the **CONFIDENTIALITY** section.

4. *If there is any intent to gather information from the subject's medical records, permission must be obtained.*

*Suggested wording:*

We may also ask you to sign a release that permits review of your medical records.

5. *If there is any intent to gather information about the subject's relatives, the subject must be informed of this intent and the type of information to be gathered should be described. Explain what measures will be taken to protect the privacy of the subject's relatives. Subjects may not be asked to release their relatives' contact information without obtaining the relatives' permission. Researchers may not contact the relatives without both the subject's and the relatives' permission.*

*Suggested wording:*

You may be asked to give us health information about your relatives. Any information you give us will be kept confidential. We will not contact your relatives without their permission. We may discuss with you the possibility of including your relatives in the study in the future.

### **SUBJECT ACCESS TO GENETIC INFORMATION:**

1. *Note that no information may be disclosed to anyone other than the subject without the subject's permission. Further, results may be disclosed to the subject or the subject's physician only if the laboratory generating the results is CLIA-approved.*
2. *If findings of any kind (e.g., results of genetic studies, clinically relevant information, or incidental findings) are to be disclosed to the subject, describe the disclosure procedures (e.g., who will make the disclosure and to whom; a referral to a genetic counselor or a referral for appropriate medical advice must be provided).*
3. *The subjects must be informed as to whether or not they will be contacted if the results of the study are found to have clinical relevance in the future or for any other reason. If the subjects are not informed that they will be recontacted in the consent document, any attempt to recontact the subject by the researcher must first be approved by the IRB.*
4. *If no disclosures are to be made, explain why.*

*Suggested wording (use all that apply):*

The results of these studies will not be made available to you because the research is still in an early phase and the reliability of the results is unknown.

If we discover new information that is important for your health care, either in this study or the future, you will be asked whether you wish to receive the results. (You may be required to have the test repeated in a clinical laboratory). Because genetic information is complex and sensitive, the results should be discussed with a genetic counselor or your primary care giver who can answer your questions or discuss your concerns (*inform subjects whether they will be responsible for the cost of repeat testing or counseling in the COSTS section*).

If you agree, we may contact you again in the future to update your information.

### **RISKS AND DISCOMFORTS:**

1. *Describe reasonably foreseeable risks, side effects, discomforts, inconveniences. Specifically consider and address the risk of breach of confidentiality or psychological trauma. Breach of confidentiality could impact insurability, employability, family plans, and family relationships. Psychological risks to consider include the impact of learning results if no effective therapy for the disorder exists or the risk of stigmatization*

*Suggested wording (use all that apply. Note that the latter is only applicable if genetic information is to be released to the subjects.):*

If the results of these studies of your genetic makeup were to be released through a breach of confidentiality, this could affect your ability to get insurance or to get or keep a job.

The results of this study could provide information about how likely it is that you or one of your children or other relatives will develop (*disorder*) in the future. This may be very upsetting because [*there is no therapy for (disorder) or the results may show that (disorder) may be passed on to children, or any other reason*].

2. *Use standard wording for venipuncture or biopsy where applicable:*

***For venipuncture:*** Blood drawing will cause some pain and carries a small risk of bleeding, bruising or infection at the puncture site.

***For biopsy (skin, muscle, fat, etc):*** Biopsy means removing a small piece of tissue from (location). Your doctor will give you a local anesthetic to numb the area to reduce the pain, and then make a cut (incision) to remove the tissue. An allergic reaction to the numbing medicine is rare (less than 1 in 10,000). Significant bleeding from \_\_\_\_\_ biopsy is rare. Infection of a \_\_\_\_\_ biopsy site may occur in up to 1 in 10 cases. A small scar will result at the biopsy site. The scar is usually much smaller than the original biopsy incision and is frequently almost invisible.

### **BENEFITS:**

1. *As appropriate, include benefits such as advancement of knowledge, clinical relevance to individual family or society, and long-term benefit if investigator intends to re-contact subjects to disclose clinically relevant information in the future.*

*Unless direct benefits to subject are assured, use the following statement: You may or may not personally benefit from participating in this study. However, by serving as a*

subject, you may contribute new information which may benefit patients in the future.

**ALTERNATIVES:**

1. *The option not to participate must be available. Also, if the study involves an experimental treatment, participants must be offered the option to participate in the treatment arm of the study without participating in the genetic or tissue storage part of the study.*

*Use one of the following statements:*

You may choose not to participate in this study.

or

You may choose not to participate in this study at all, or you may choose to participate in the part of the study involving the experimental treatment without participating in the [genetic study/tissue bank/etc.].

**CONFIDENTIALITY:**

1. *Explain how information will be kept confidential, both at OHSU and upon transfer to any other laboratory or institution. NOTE: Studies that involve the transfer of identified samples to other researchers will not be approved unless a compelling justification for the retention of the identifiers is provided.*
2. *If information/samples will be transmitted outside OHSU, indicate who the recipient(s) will be.*

*Suggested wording (use all that apply):*

Your samples will be labeled with [your name or other information, such as medical record number, SSN, etc. (specify)] that will identify you.

Other investigators who may receive samples of your [blood/tissue/genetic information/medical information] for research will also be given information that may identify you or your family members.

or

A code number will be assigned to you, your cells and genetic information, as well as to information about you. Only the investigators named on this consent form will be authorized to link the code number to you. Other investigators who may receive samples of your [blood/tissue/genetic information/medical information] for research will be given only the code number which will not identify you.

or

All identifying information about you will be removed from the samples before they are released to any other investigators.

3. *State:* All other parties including employers, insurance companies, personal physicians, and relatives will be refused access to the information or to the samples, unless you provide written permission, or unless we are required by law to do so.
4. *State:* Neither your name nor your identity will be used for publication or publicity purposes.
5. *Where applicable, state:* Research records may be reviewed and/or copied by [use all that are applicable: the sponsor, the OHSU IRB, the Food and Drug Administration, or any other applicable agency].
6. *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.
7. *If video/audio tapes or photographs are being used for research purposes, indicate whether or not subjects will be identifiable, or how identity will be concealed. Also, indicate how long the tapes/photographs will be stored, and what will be done with them upon completion of the study. (For identified recordings used that will be publicly displayed, such as teaching, research presentations, marketing, etc. please see Media Consent Form).*

### **COSTS:**

1. *If there are no costs to the subjects, state that explicitly.*
2. *Inform subjects of costs not covered, such as the costs of genetic counseling. If results will need to be repeated in a clinical laboratory, those costs must also be mentioned. Subjects should also be informed of the implications, including potential insurability, of authorizing disclosure to a third party payer that the genetic test was performed, and that he/she has the option of paying the cost of the genetic test out of pocket rather than filing an insurance claim.*

### *Suggested wording:*

There will be no cost to you for participating in this research. If the results are important for your health care, you will be asked to have the tests repeated in a clinical laboratory. The costs for the repeat testing and the counseling necessary to be certain that you understand what the results mean may be billed to you or to your third party carrier. (Caution: This will probably make the results available to the third party carrier and to your clinical record. You may choose to pay out of pocket instead.)

3. *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.*

**COMMERCIAL DEVELOPMENT:**

1. *Unless this statement is included in the consent form, no commercial development of products based on the collected samples can take place without specific re-consent of subjects:*

By consenting to participate, you authorize the use of your samples for the research described in the PURPOSE and PROCEDURES sections of this document. In addition, you acknowledge that [OHSU or the sponsor, as appropriate] may make any lawful use of your samples, including, but not limited to, future research studies, destroying them, or transferring them to a public or private entity.

Samples obtained from you in this research may be used to make a discovery that could be patented or licensed to a company. There are no plans to provide financial compensation to you should this occur. However, should [OHSU or the sponsor, as appropriate] ever provide your samples to anyone else for research or commercial use, it will do so in such a way as to protect your privacy and confidentiality as stated in the CONFIDENTIALITY section of this document. Further, you will have no responsibility or liability for any use that may be made of your samples.

**LIABILITY:**

*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. *You must include one of the following statements:*

The [blood/tissue samples/genetic or other information] that we will collect from you in this study will not be stored with your name or any other identifier. Therefore, there will not be a way for us to identify and destroy your materials if you decide in the future that you do not wish to participate in this research.

or

If in the future you decide you no longer want to participate in this research, we will destroy all your [blood/tissue samples/genetic or other information]. However, if your genetic samples are already being used in an on-going research project and if their withdrawal jeopardizes the success of the entire project, we may ask to continue to use them until the project is completed.

or

If in the future you decide you no longer want to participate in this research, we will remove your name and any other identifiers from your [*blood/tissue samples/genetic or other information*], but the material will not be destroyed and we will continue to use it for research.

2. *State:* [Name] (503) 494-####) has offered to answer any other questions you may have about this study. If you have any questions regarding your rights as a research subject, you may contact the OHSU Research Integrity Office at (503) 494-7887.
3. *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.
4. *If the investigator is also the patient's health care provider state:* Your health care provider is [one of the] investigator[s] of this research protocol, 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 associated with this project. You are not under any obligation to participate in any research project offered by your physician.
5. *Clarify under what circumstances the subject may be removed from the study prior to study conclusion (i.e., investigator's discretion, sponsor's discontinuation, pregnancy, serious side effects, progression of disease, failure to respond to treatment, subject's failure to comply with instructions etc.).*
6. *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.*
7. *Indicate what will happen if a subject chooses to withdraw (e.g., list the visits and/or procedures the subject will be requested to complete).*
8. *For studies recruiting OHSU students as participants, please include the following statement:* The participation of OHSU students 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.
9. *Include a statement that the person signing the consent form will be given a copy.*
10. *A Child Assent Form should be attached to the consent form, if the study subject is a child between 7 and 18.*

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

**SIGNATURES:**

1. *If you intend to remove identifiers in order to keep the subject's sample in the event that the subject wishes to no longer participate in the research project, you must include the following statement with a check box or line for subject's initials:*

If in the future I decide that I no longer wish my blood/tissue sample to be used in this research study with information that can identify me, I agree that my blood/tissue sample may continue to be used for anonymous research by removing all identifying information from my sample.

2. *If you or the sponsor wishes to store the subject's sample for potential future use beyond the current study, a tiered consent form should be used. In the tiered consent form, different options are presented at the end of the consent form, but prior to the signature lines, and participants sign or place their initials next to their preferred options. Some suggested wordings with increasing levels of permission follow; note that these options are mutually exclusive and that participants must choose one of the options.*

I give my consent to participate in the treatment part of this study, but I do not give my consent for the storage and future use of my blood/tissue samples.

I give my consent for my blood/tissue samples to be stored and used for this study only.

I give my consent for my blood/tissue samples to be used for this study and stored for possible use in future studies of *(state whether the future research would be for a related purpose or may include research on unrelated health problems and give examples)*, but I wish to be contacted for permission prior to any future use.

I give my consent for my blood/tissue samples to be used for this and future studies of *(state whether the future research would be for a related purpose or may include research on unrelated health problems and give examples)*, and do not need to be contacted for permission in the future.

3. *The last paragraph should be:* Your signature below indicates that you have read the foregoing and agree to participate in this study.
4. *Include signature lines and date lines for the subject and the person obtaining consent, preferably the investigator. Where pertinent (children, cognitively impaired, etc.) lines for parent and/or guardian should be included. Consent regulations for 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]. Signature lines for witnesses are not required by the OHSU IRB, but may be included if required by the study sponsor.*