Washington State Institutional Review Board (WSIRB)

Consent: Sample Format

**Researcher Contacts**

PI or Study Coordinator name, complete address, phone number (collect or toll-free), (provide 24 hour number if drug or device), and email address.

**Key Information in Beginning of Consent Form**

The Revised Common Rule contains a new requirement of a new section containing a concise presentation of key information. This will assist in the subject in understanding the reasons why one might or might not want to participate in the research. It must be organized and presented in a way that facilitates comprehension. WSIRB requires this key information section only if your consent form is longer than four pages.

**Why is the research taking place?**

• State that the activity is research and explain why the study is being conducted.

• Must include the word “research”

• Explain why the individual is eligible for the research. Indicate the anticipated number of subjects.

• Funded research: Specify the funding agency/institution.

• Student research: State that the research will be conducted to fulfill requirements for a degree. Specify the institution and program.

**What would I be asked to do?**

• Describe study procedures. Distinguish between procedures conducted for research purposes only and procedures conducted as part of routine/standard service delivery or care.

• If applicable: Explain how randomization would be performed. Explain the specific research procedures/services for each group.

• Identify who will conduct study procedures.

• Identify where study procedures will take place.

• Estimate the time required for study procedures, and indicate the expected duration of active participation over time.

• If surveys and/or interviews will be administered, state that there may be personal and sensitive questions.

• Describe any confidential records requested for the research.

**Delineating Future Plans**

• Per the Revised Common Rule, researchers must now carefully consider their future plans for use of the data or specimens beyond the primary study. This must be specifically addressed as a new additional element in the consent form. This cannot be a “dumping ground” for all future uses, and the use must be carefully conscribed.

• Research collecting identifiable private information and/or identifiable private biospecimens must:

• State that collected data (or samples) may be de-identified and used for future research or be given to another investigator without the subject being informed through a consent process, or

• State that collected data will not be used or distributed for future research even if de-identified.

**What are the possible risks or harms if I take part?**

• Describe the physical, psychological, social, and/or economic risks or discomforts (including invasion of privacy) of the research in terms of type, probability, magnitude, and duration.

• Explain how risks will be minimized.

• Explain what will happen if subjects experience adverse events. Indicate whom subjects should contact and how.

• If applicable, explain that the research may involve risks to the participant (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable.

• If applicable, a risk of possible loss of confidentiality.

**What are the possible benefits?**

Describe the expected benefits for individual subjects, the class of subjects, and/or to society. If there may be no benefits for the individual subject, state this explicitly. (Payment offered for participation is not a research benefit.)

**What are my choices if I don’t take part?**

• State that study participation is voluntary. State that subjects may refuse to participate or withdraw from the study at any time without penalty or losing any services or benefits to which they are otherwise entitled.

• If applicable: Describe any alternative procedures or standard care available to the subject.

• If applicable: Explain the consequences of a subject’s decision to withdraw from the research and procedures for study withdrawal.

**Who would see study information about me?**

• Specify who will have access to identifiable study information.

• Describe procedures for protecting confidentiality of study information.

• Explain where and how study information will be stored. State when identifiers and/or identifiable data will be destroyed.

• State whether study data without identifiers could be given to other researchers.

* States that if the results of the trial are published, the subject's identity will remain confidential.

**Would I be paid for my time? Will the study cost me anything?**

• Explain whether subjects will be offered payment. Describe the form of payment and when it will be provided. Indicate whether pro-rated payment will be provided if subjects do not participate in all study procedures.

• Specify any costs subjects may incur, either immediately or long-term.

• If study involves greater than minimal risk, explain whether any medical treatments are available in the event of injury. If so, describe the treatment(s) and whether their cost will be paid by the researcher or the subject.

**What else do I need to know?**

• State that the subject is not required to answer all questions or complete all study procedures.

• If applicable: State that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject.

• If applicable: Describe circumstances under which the subject’s participation may be terminated by the investigator without the subject's consent.

• If applicable: State that all suspected abuse/neglect of children will be reported to Child Protective Services.

* If applicable: State that all suspected abuse of dependent adults will be reported to Adult Protective Services.

• If applicable: State that if a subject indicates that he/she may harm himself or other people, research staff will call the Crisis Line, or the local police if there is immediate danger.

• If applicable: Explain plans to report notifiable condition(s), specify the condition(s) to be reported, and the entity to which it would be reported. See WAC 246-101 for list of conditions that need to be reported.

• If applicable: When the research includes obtaining and/or using biospecimen sample(s), the consent form must now state whether the research will or might including genome or exome sequencing.

• If applicable: When the research including obtaining and/or using biospecimen samples there must be a statement that the biospecimens, even if de-identified, may be used for commercial profit and that this commercial profit will not be shared.

• If applicable: There must be a statement regarding whether clinically relevant research results will be given to the subject and under what conditions.

• State that the subject may call the investigators toll-free or collect if he/she has any questions, concerns or complaints about the research, or feel they have been harmed or injured by participating. Include the telephone number.

• Include verbatim: "You may call the Washington State Institutional Review Board if you have questions about your rights as a research subject, or questions, concerns, or complaints about the research. The WSIRB oversees this study to make sure that the rights of people who take part are protected. You can call 1.800.583.8488 or email wsirb@dshs.wa.gov. You don't have to give your name."

* If applicable: 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 website at any time.

Printed Name of Subject

Subject Signature Date

Parent / Guardian Signature (If Applicable) Date

Witness/Advocate Signature (If Applicable) Date

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date

Copies to: Subject

Investigator’s File

Case File/Medical Record (if applicable)