**WASHINGTON STATE UNIVERSITY**

[Insert name of department/college here]

**Research Study Consent Form**

**Study Title:** [Title as listed on IRB application]

**Researchers:**

List names, academic/staff positions, divisions/departments, telephone numbers of ALL Primary Investigators and Co-Investigators

**NOTE:** Students should be listed as Co-Investigators with their advisor as PI

For studies involving more than minimal risk, include a 24-hour emergency telephone number with name or position (when relevant)

**Sponsor:** [Delete if not applicable]

**Financial Conflict of Interest:** [Delete if not applicable] The Washington State University Financial Conflict of Interest committee has evaluated the management plan to reduce the possible effects of this relationship on human subject safety and welfare.

**External Funding:** [Delete if not applicable]

For Consent Forms **over** 2,000 words:

As of January 21, 2019 Federal Law requires that subjects be given a concise and focused presentation of key study information before being given other information. The goal of this section is to assist potential subjects with understanding the reasons why one may or may not want to participate in the research.

For Consent Forms **under** 2,000 words:

If the consent form is thorough, the Key Information Section may be deleted, so long as the same information is covered elsewhere in the consent form.

**KEY INFORMATION ABOUT THIS STUDY**

[Use the bullet points below and keep the formatting.]

* Your consent is being sought for research. Participation is voluntary.
* Study Purpose – A brief summary.
* Major Activities of Subject Participation – Activities the subject will have to complete or avoid.
* Duration of Participation – Time and length.
* Significant Risks – Those that are most likely or concerning.
* Potential Benefits – Those that are most likely.
* Alternative Procedures – Include alternative treatments or assignments.
* This is a clinical trial and should not be considered medical treatment.
* Whether the research includes whole genome sequencing.
* Any other important information

**What you should know:**

You are being asked to take part in a research study carried out by [name of PI and co-PIs]. This form explains the research study and your part in it if you decide to join the study. Please read the form carefully, taking as much time as you need. Ask the researcher to explain anything you do not understand. Your participation in the study is voluntary. You can decide not to join the study. If you join the study, you can change your mind later or quit at any time. You may refuse any question, test, or procedure. There will be no penalty or loss of services or benefits if you decide to not take part in the study or quit later. This study has been approved for human subject participation by the Washington State University Institutional Review Board.

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

This research study is being done to [Briefly describe the primary purpose of the study in lay language.]. This is a clinical trial, not a treatment. There are the following alternative treatments….

You are being asked to take part because [include a reason why the participant is being asked to participate (e.g.,…you are a person with a chronic illness)].

You cannot take part in this study if [list exclusion criteria (e.g, you are under 18, you are taking anti-depressants, you are involved in any other research study at this time, etc).]

Note:If your study involves incomplete disclosure or deception, an alteration of consent must be applied for on your IRB application. Submit a debriefing form to be used when explaining the true purpose of the study to participants after completion.

**What will I be asked to do if I am in this study?**

If you take part in the study, you will be asked to Provide a complete description of procedures, including:

* Each specific step involved and the chronological order in which they will occur
* Taking part in the study will take about (total minutes, hours, weeks, months, or years).
* The estimated amount of time each step will take and duration of participation
* The names of any medications or substances to be given
* The size or amount of biological samples to be taken or doses to be given (in common household measurements such as teaspoons)
* Explain randomization and/or placebo if applicable.
* A description of questionnaires, surveys, and interviews and include examples of the most personal or sensitive information you will be seeking or questions
* A description of the use of medical, academic or other records or data being used in the study
* A statement that you will be using voice, video, digital or image recordings. Explain how long they will be stored, what they will be used for, if they will be shared with others, if they will be used in presentations or publications, and whether the subject will be able to review and delete portions.
* An explanation of any aspect of the procedures that are experimental.
* In studies involving access to medical records or protected health information advise participants they will need to sign Addendum 7 - HIPAA Authorization Form and Appendix A for use or creation of personal health information (PHI) in research (http://www.irb.wsu.edu/forms.asp.)
* A statement letting participants know they can opt out of having any clinically relevant research results or incidental findings given to the participant, their physician, or any other person or institutions.
* [Delete the following if not applicable] This research involves whole genome sequencing.
* [If applicable insert this statement] If significant new findings develop during the course of the research which may relate to your willingness to continue participation, these will be provided to you and you can decide whether to continue participating.
* The estimated number of subjects in the study.

**Additional Privacy Protections or European Union General Data Protection Regulations** [Remove this section if not applicable.]

* If research is subject to the GDPR, the consent must list all types of data collected, who will have access, and if the data will be transferred to a third party.
* If research is subject to the GDPR, specifically list if any of the following data will be collected: racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, processing of genetic data, biometric data for the purposes of unique identification, health data, information on the subject’s sex life or sexual orientation.
* If research is subject to the GDPR, ensure that no member state has enacted additional protections or disclosures that must be made.
* If research is subject to the GDPR, the subject’s rights to access, rectify, and erase personal data as well as the subject’s rights to restrict or object to processing personal data.
* If research is subject to another country or state’s privacy regulations, ensure that those are appropriately followed in the IRB protocol and conveyed here to subjects.

**Are there any benefits to me if I am in this study?**

The potential benefits to you for taking part in this study are: [Describe only those that are likely for research participants. Do not overstate potential benefits.]

[If there are none, state] There is no direct or intended benefit to you from being in this study.

Describe generalizable or societal benefits in a sentence such as: [If you take part in this study, you may help others in the future.]

Note: Do not include financial payment, course credit, or other forms of incentive as benefits of being in the project. This information belongs in the section on costs or payments.

**Are there any risks to me if I am in this study?**

The potential risks from taking part in this study are…. [Do not state that there are no risks or that risks “should be minimal.” In addition to physical risks/discomforts or stress, describe any other risks, such as:

* Psychological, economic, social, employment, reputation, or loss of confidentiality or sensitive information.
* Include risks associated with sensitive questions, for example, distress or discomfort, or include sample questions.
* If applicable, include risks of reporting illegal or reportable behavior (abuse, suicide or intent to harm).
* State if there is no medical treatment or are no funds allotted for compensation for study related injuries.
* [Include this statement for studies with minimal risk or less (Exempt, Expedited, or Limited Review)] As with any experimental procedures, there may be adverse events or side effects that are currently unknown.
* [Include this statement for studies involving greater than minimal risk (Full Board)]  As with any experimental procedure, there may be adverse events or side effects that are currently unknown and it is possible these unknown risks could be permanent, severe or life-threatening.
* [Include this statement if conducting FDA research on a controlled drug/device trial.] A description of this clinical trial will be available on <http://www.ClinicalTrials.gov> as required by U.S. Law. This website will not include information that can identify you. At most, it will include a summary of the results. You may search this website at any time.
* There may be unforeseeable risks to the embryo or fetus, if you are or become pregnant.
* Explain if there are any anticipated circumstances under which participation may be terminated by the researchers.
* Describe the precautions that are being taken to minimize risks and steps that will be taken if risks occur. If applicable, discuss the availability of referrals, counseling, or other services, such as suicide counseling.

**Will my information be kept private?**

For data collected anonymously:

The data for this study are being collected anonymously. Neither the researcher(s) nor anyone else will be able to link data to you.

[or]

For data collected with identifiers:

The data for this study will be kept confidential to the extent allowed by federal and state law. Under certain circumstances, information that identifies you may be released for internal and external reviews of this project.

* If data are coded and a key maintained separately, inform participant of the process.
* Explain how you will maintain the participant’s privacy throughout the study (e.g. private conversations, interaction with other participants, a private location)
* Describe where data will be stored and how it will be protected.
* Inform participants if voice, video, digital or image recordings will be made of them, and indicate if this is required to be in the study. If not required, a separate check box must be included with the signature at the end of the form
* Describe who will have access to the data, including:

All researchers and research staff

Institutional Review Board (IRB)

Sponsors, agencies, or regulatory bodies (NIH, FDA, etc.) If the FDA is a sponsor, state that they will have access to medical records in a directed or routine audit of the investigator, the institution, or the IRB.

HRPP staff for post-approval review

Designated data custodians (both IT ATO for data destruction and person who has backup access)

* Explain focus group confidentiality (if applicable)
* For International Research: Monitors, auditors, IRB personnel, and regulatory authorities may be granted direct access to your original medical records for verification of clinical trial procedures and data, without violating your confidentiality to the extent permitted by the applicable laws and regulations. By signing this document you are authorizing this access. If results of this study are published, your identity will remain confidential.

[If applicable]The results of this study may be published or presented at professional meetings, but the identities of all research participants will remain anonymous.

[If applicable] Identifiers might be removed from the identifiable private information or identifiable specimens and then the information or specimens could be used for future research studies or distributed to other researchers for future research studies without your additional permission. If you do not agree to this, you may choose to not join the study.

The data for this study will be kept for \_\_\_ years [a minimum of 3 years after the completion of the study is required by WSU]. [If the length of time cannot be determined, include the criteria that will be used to make the determination.]

If applicable, discuss reporting of the following (e.g., potential or actual harm - to self or others, child abuse, elder abuse, or other reports that may be made).

**National Institutes of Health Certificate of Confidentiality** [Delete entire section if researchers do not have NIH funding.]

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or bio-specimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.   
  
[Use the following language as applicable] The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by [THE AGENCY] which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).  You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of [list what will be reported, such as child abuse and neglect, or harm to self or others in response to specific federal, state, or local laws ].

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document [Restate what will be disclosed, such as including research data in the medical record].

**Are there any costs or payments for being in this study?**

[If applicable] There will be no costs to you for taking part in this study. [or] Explain if the costs of the medical treatment in the study will be billed to the subject or their health insurance. Identify any other anticipated costs as well.]

[If applicable] You will receive \_\_\_\_\_ for taking part in this study. [If payment is via gift card, specify the type of card.] If you decide to quit the study you will receive \_\_\_\_\_. [Specifically explain the method or schedule for each payment.]

[If applicable] If you receive payment for taking part in this study, you may be asked to provide your home address or social security number.

[or]

You will not receive money or any other form of compensation for taking part in this study. [If applicable] The information or bio-specimens that are collected as part of this research may be used for commercial profit. There is no plan to share this profit with you.

[or]

As a student, you will receive credit or extra credit in the amount of \_\_\_\_\_\_\_\_. [If applicable You have the choice to complete: (equivalent, non-research assignment) instead which may be completed in place of research participation.]

**Who can I talk to if I have questions?**

If you have questions about this study or the information in this form, please contact the researcher [Name and complete contact information: mailing address, e-mail address, and phone number(s)]. If you have questions about your rights as a research participant, or would like to report a concern or complaint about this study, please contact the Washington State University Institutional Review Board at (509) 335-7646, or e-mail irb@wsu.edu, or regular mail at: Neill 427, PO Box 643143, Pullman, WA 99164-3143.

**What if I have a study-related injury or want to withdraw?**

[If the research involves the potential for injury, one of the following three statements regarding appropriate compensation for injury must be included]

[Option 1 - Non-Sponsor Funded Compensation]

While it is not expected that participation in this study would lead to additional medical costs it is possible that you could have an event that would necessitate medical care. In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think you have a study related injury, illness, distress and want to report this to the researchers, contact [Name and complete contact information: mailing address, e-mail address, and phone number(s)]. In order to withdraw your previously collected data from the study you must [include instructions here]. [If there are consequences for withdrawing from the research state them here.]

[Option 2 - Sponsor Funded Compensation]

While it is not expected that participation in this study would lead to additional medical costs it is possible that you could have an event that would necessitate medical care. In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. The sponsor of the study has some funds available to pay for care for injuries resulting directly from being in this study. If you think you have a study related injury and that you may be eligible for reimbursement of some medical care costs, contact [Name and complete contact information: mailing address, e-mail address, and phone number(s)] right away. In order to withdraw your previously collected data from the study you must [include instructions here]. [If there are consequences for withdrawing from the research state them here.]

[Option 3: If the preferred injury compensation language is unacceptable to the study sponsor, the following alternative language may be used.]

While it is not expected that participation in this study would lead to additional medical costs it is possible that you could have an event that would necessitate medical care. In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. Under some circumstances the sponsor of the study will pay for care for injuries resulting directly from being in the study. If you want information about those circumstances or if you think you have suffered a research related injury contact the study physicians right away: contact [Name and complete contact information: mailing address, e-mail address, and phone number(s)] In order to withdraw your previously collected data from the study you must [include instructions here]. [If there are consequences for withdrawing from the research state them here.]

**What are my rights as a research study volunteer?**

Your participation in this research study is completely voluntary. You may choose not to be a part of this study. There will be no penalty to you if you choose not to take part. You may choose not to answer specific questions or to stop participating at any time. You will be given a copy of the consent form for your records.

**What does my signature on this consent form mean?**

Your signature on this form means that:

* You understand the information given to you in this form
* You have been able to ask the researcher questions and state any concerns
* The researcher has responded to your questions and concerns
* You believe you understand the research study and the potential benefits and risks that are involved.
* You are giving your voluntary consent to take part in the study.

**Statement of Consent [Remove sections that do not apply.]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Yes,**  **I agree** | **No,**  **I disagree** | | |  |
|  | |  | The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team. | |
|  | |  | The researcher may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the investigator will attempt to limit such identification. I understand the risks associated with such identification. | |
|  | |  | The researcher may retain any leftover blood or tissue samples taken during the study. These samples may be used for other research not related to this study. These samples will be retained in de-identified form, meaning that there will be no information associated with the blood or samples that will allow anyone to readily ascertain my identity. I will not be re-contacted for permission to use the samples. | |

**[There are three sets of signature options listed below. Use the signature block appropriate for your study. Delete those that do not apply. Omit the signature page if there is no written documentation of consent.]**

**Signature Block for Capable Adult:**

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

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Signature of Participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Obtaining Consent

**Signature Block for Witness:**

**WITNESS STATEMENT:**

The participant was unable to read or sign this consent form because of the following reason:

The participant is illiterate

The participant is visually impaired

The participant is physically unable to sign the consent form. Please describe:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Other (please specify):

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My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Witness to Consent Process Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Witnessing Consent Process

**Signature Block for Adult Unable to Consent:**

Your signature documents your permission for the named participant to take part in this research.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Legally Authorized Representative Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Legally Authorized Representative Date

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Signature of Person Obtaining Consent Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Person Obtaining Consent Date

Note: For lower risk studies or studies with a large number of participants (mass administered questionnaires, etc.) it may be permissible for the PI to sign and date one copy and make copies of the informed consent document for participants.