**Consent for Research Participation**

**Title:** [Title]

**Sponsor:** [Name of Study Sponsor, if sponsored. If no sponsor, delete this line]

**Researcher(s):** [Name], [Institution (e.g., University of Oregon)]

 [Name], [Institution (e.g., University of Oregon)]

**Researcher Contact Info:** [Phone]

 [Email]

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

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| **Key Information for You to Consider** |
| * **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
* **Purpose**. The purpose of this research is [provide a brief description of why the research is being conducted, no more than 2-3 sentences].
* **Duration.** It is expected that your participation will last [expected duration].
* **Procedures and Activities.** You will be asked to [briefly highlight the key research activities/procedures].
* **Risks.** Some of the foreseeable risks or discomforts of your participation include [describe the most important risks. Consider those most probable and/or highest magnitude of harm].
* **Benefits**. Some of the benefits that may be expected include [insert direct benefits, or if no direct benefit to subject state no direct benefit but the researchers hope to learn/gain xyz].
* **Alternatives.** As an alternative to participation, you could [note appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject. If there are no alternatives, state that, “Participation is voluntary and the only alternative is to not participate.”].
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Who is conducting this research?

[Note: This section to be included when multiple institutions are collaborating and/or when a member of the research team has a conflict of interest.]

The researcher(s) [(Name)] from [Institution Name (e.g., University of Oregon, etc.)] are asking for your consent to this research. [See guidance document for language to insert when a conflict of interest needs to be disclosed].

Why is this research being done?

[NOTE: If the full purpose is described in the key information summary above, this section may be deleted.]

The purpose of the research is [describe purpose of the study in simple terms]. You are being asked to participate because [see guidance document for language to insert]. About [number] people will take part in this research.

How long will I be in this research?

[NOTE: If duration is fully detailed in the key information summary above, delete this section.]

We expect that your participation will last [see guidance document for language to insert].

What happens if I agree to participate in this research?

[NOTE: If all procedures/activities are described in the key information summary above, delete this section.]

If you agree to be in this research, your participation will include [see guidance document for language to insert].

We will tell you about any new information that may affect your willingness to continue participation in this research.

What happens to the information collected for this research?

Information [and/or specimens] collected for this research will be used to [see guidance document for language to insert].

[See guidance document for additional language to insert].

How will my privacy and data confidentiality be protected?

We will take measures to protect your privacy including [see guidance for language to insert]. Despite taking steps to protect your privacy, we can never fully guarantee your privacy will be protected.

We will take measures to protect the security of all your personal information including[see guidance for language to insert]. Despite these precautions to protect the confidentiality of your information, we can never fully guarantee confidentiality of all study information.

Individuals and organization that conduct or monitor this research may be permitted access to and inspect the research records. This may include access to your private information and [include any other records]. These individuals and organizations include: [see guidance document for language/list to insert]

If the research involves the collection of identifiable private information and/or identifiable biospecimens, one of the following statements must be included:

* Identifiers might be removed from identifiable private information and/or identifiable biospecimens collected in this research. After removal of identifiers, the information and/or biospecimens may be used for future research or distributed to another investigator for future research without obtaining additional consent. – OR -
* Information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

[see guidance document for additional language to insert]

What are the risks if I participate in this research?

[NOTE: If all risks are disclosed in the key information summary above and/or are limited to breach of privacy and/or confidentiality, you may remove this section.]

The risks or discomforts of participating in this research include [see guidance document for language to insert].

[see guidance document for additional language to insert]

What are the benefits of participating in this research?

[NOTE: If all benefits are disclosed in the key information summary above,, this section may be deleted.]

You may or may not benefit from participating in this research. [see guidance document for language to insert].

What are my responsibilities if I choose to participate in this research?

[Include this section only when applicable, otherwise, it may be deleted.]

If you take part in this research, you will be responsible for: [see guidance document for language to insert].

What other choices do I have besides participation in this research?

[NOTE: If there are no alternatives or these have been fully disclosed in the key information summary above, you may remove this section.]

It is your choice to participate or not to participate in this research. [see guidance document for language to insert].

What if I want to stop participating in this research?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your relationship ­­with the researchers or the University of Oregon.

[see guidance document for additional language to insert].

Will it cost me money to take part in this research?

[Include this section only when a participant may potentially question if there are costs associated with participation, otherwise, it may be deleted.]

[see guidance document for language to insert].

What if I am injured because of participating in this research?

[This section must be included for any study that is greater than minimal risk or when the study involves the possibility of injury. Delete if not applicable.]

If you are injured or get sick because of being in this research, call the researchers immediately.

[see guidance document for additional language to insert].

If you experience harm because of the project, you can ask the State of Oregon to pay you. If you have been harmed, there are two University representatives you need to contact. Here are their addresses and phone numbers:

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| --- | --- |
| **General Counsel/ Office of the President** |  **Research Compliance Services** |
| 1226 University of Oregon |  5237 University of Oregon |
| Eugene, OR 97403-1226 |  Eugene, OR 97403-5237 |
| (541) 346-3082 |  (541) 346-2510 |

A law called the Oregon Tort Claims Act may limit the amount of money you can receive from the State of Oregon if you are harmed.

Will I be paid for participating in this research?

[see guidance document for language to insert].

Who can answer my questions about this research?

If you have questions, concerns, or have experienced a research related injury, contact the research team at:

|  |
| --- |
| [Insert Name of PI] |
| [Phone number that is answered/attended to regularly] |
| [Confidential email that is answered/attended to regularly] |

An Institutional Review Board (“IRB”) is overseeing this research. An IRB is a group of people who perform independent review of research studies to ensure the rights and welfare of participants are protected. UO Research Compliance Services is the office that supports the IRB. If you have questions about your rights or wish to speak with someone other than the research team, you may contact:

|  |
| --- |
| Research Compliance Services |
| 5237 University of Oregon |
| Eugene, OR 97403-5237 |
| (541) 346-2510 |

**STATEMENT OF CONSENT**

I have had the opportunity to read and consider the information in this form. I have asked any questions necessary to make a decision about my participation. I understand that I can ask additional questions throughout my participation.

I understand that by signing below, I volunteer to participate in this research. I understand that I am not waiving any legal rights. I have been provided with a copy of this consent form. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

[See guidance for additional initial spaces and language to insert when applicable]

I consent to participate in this study.

Name of Adult Participant Signature of Adult Participant Date

**Researcher Signature** (to be completed at time of informed consent)

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

Name of Research Team Member Signature of Research Team Member Date