**University of Oregon [SAMPLE] Consent Form**

This standard Consent format has been adopted by the IRB to assist researchers in developing easy-to-read consent documents. The format may be modified or expanded, but the consent form is to contain all the elements included below. The brackets [ ] are areas for customizing the form according to the purpose and procedure of your study. Please use language which the average lay person is likely to understand or which is appropriate for the age of the subjects (specifically on child assent forms Starred (\*) items may be omitted if they do not apply). For reference on plain language writing see http://www.plainlanguage.gov/index.cfm and for plain language biological terms see the CDC’s Plain Language Thesaurus for Health Communication at <http://depts.washington.edu/respcare/public/info/Plain_Language_Thesaurus_for_Health_Communications.pdf>.

**University of Oregon** [*School or Department name*]

**Informed Consent for Participation as a Subject in** [*Title of Study*]

**Investigator:** [*name of PI*]

**Type of consent** [*Adult Consent Form or other applicable consent form such as Child Assent Form Ages 12-17*]

**Introduction**

* You are being asked to be in a research study of [*insert general statement about study*].
* You were selected as a possible participant because [*explain how subject was identified, include any exclusionary criteria*].
* We ask that you read this form and ask any questions that you may have before agreeing to be in the study.

**Purpose of Study:**

* The purpose of this study is [explain research question and purpose in lay language].
* Participants in this study are from [state what area(s) they are from] OR The total number of subjects is expected to be [insert number].
* \*Please note that the responsible investigator and/or other members of the research team have a significant financial interest in [choose one: the sponsor of this research OR the product being investigated in this study OR other appropriate statement].

**Description of the Study Procedures:**

* If you agree to be in this study, we would ask you to do the following things: [explain procedures and tasks; identify any procedures that are experimental; describe length of time for participation, frequency and duration of procedures; etc.]
* \*[If applicable, explain any alternative procedures or courses of treatment available to the subject this DOES NOT APPLY TO MOST STUDIES AT UO]

**Risks/Discomforts of Being in the Study:**

* The study has the following risks. First, [explain first risk, including the likelihood of the risk]. Second, [explain second risk, including the likelihood of the risk]. Third, …
* [If there are no foreseeable risks, state as such] There are no reasonable foreseeable (or expected) risks. This study may include risks that are unknown at this time.

**Benefits of Being in the Study:**

* The purpose of the study is [briefly state]
* The benefits of participation are [explain benefits of participation that will be gained by the participants and/or other. If a benefit is not likely to occur to each participant do not include.]
* [If there are no expected benefits, state as such.]

**Compensation:**

* You will receive the following reimbursement: [explain amount of reimbursement (e.g., cash, voucher, class points, donations, etc.), as well as when reimbursement will occur and in what cases it will not occur if any. If there will be no payment, state this.]
* Please note, compensation from participation in Human Subjects Research studies may be considered taxable income.  Compensation amounts are tracked across all studies in which you participate. If compensation totals $600 or more in a calendar year, the University is required to report the income to the IRS.  University departments are required to track participant compensation and may contact you to complete a W9 form for tax reporting purposes.   Because of this, your name will be associated with participation in a research study. Department and university administrators will have access to this information, but will not have access to research data.

**Costs:**

* There is no cost to you to participate in this research study.
* OR for studies involving medical treatments
* There is no cost to you to participate in this research study, however, the cost of [insert lab test, procedure, etc.] will be billed to your insurance company and we will accept as full payment whatever they pay us. OR
* How much you will have to pay depends on whether or not you have medical insurance and what costs your insurance will cover. You or your insurance carrier will be responsible for the costs of [insert what tests, treatments, visits, etc.].

**Confidentiality:**

* The records of this study will be kept private. In any sort of report we may publish, we will not include any information that will make it possible to identify a participant. Research records will be kept in a locked file.
* All electronic information will be coded and secured using a password protected file. [If audio or video tape recordings are made, explain specifically who will have access to them, if they will be used for educational purposes, and when they will be erased/destroyed and indicate how they will be destroyed or erased]
* Access to the records will be limited to the researchers; however, please note that [if applicable sponsors or funding agencies] regulatory agencies, and the Institutional Review Board and internal University of Oregon auditors may review the research records.
* For Genetic Research add

**Voluntary Participation/Withdrawal:**

* Your participation is voluntary. If you choose not to participate, it will not affect your current or future relations with the University [or with other institutions (insert name)].
* You are free to withdraw at any time, for whatever reason.
* There is no penalty or loss of benefits for not taking part or for stopping your participation. [For studies with students, state that the subject does not jeopardize grades nor risk loss of present or future faculty/school/University relationships [Explain any consequences (e.g., adjusted monetary benefits) due to early withdrawal.]
* \*You will be provided with any significant new findings that develop during the course of the research that may make you decide that you want to stop participating.

**\*Dismissal From the Study:**

* The investigator may withdraw you from the study at any time for the following reasons: (1) withdrawal is in your best interests (e.g. side effects or distress have resulted, (2) you have failed to comply with the study requirements, or (3) the study sponsor decides to terminate the study.

**Contacts and Questions:**

* The researchers conducting this study are [insert name(s) of investigators, including the PI]. For questions or more information concerning this research you may contact her/him/them at [telephone number or other way to contact person].
* If you believe you may have suffered a research related injury, contact [specify name, usually researcher] at [telephone number] who will give you further instructions.
* If you have any questions about your rights as a research subject, you may contact: Research Compliance Services, University of Oregon at (541) 346-2510 or ResearchCompliance@uoregon.edu

**Copy of Consent Form:**

* You will be given a copy of this form to keep for your records and future reference.

**Statement of Consent:**

*(Choose only one statement according to type of consent or assent form)*

* For Adult Consent Form or older child (12-17 years) combined Consent/Assent (Full form): I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent to participate in this study. I have received (or will receive) a copy of this form.
* For Child Assent Form: This form was read to the subject and/or the subject has read this form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information.
* For Parental Permission/Consent Form: I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I give my consent for my child to participate in this study. I have received (or will receive) a copy of this form.

**Signatures/Dates**

[*delete those below that do not apply to your protocol*]

[*For Adult or Subject's Legal Representative or older child consent (Full Form):*]

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**Study Participant (Print Name)**

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**Participant or Legal Representative Signature Date**

[*For Adult or Subject’s Legal representative or older child consent (Short Form):*]

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**Study Participant (Print Name)**

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**Participant or Legal Representative Signature Date**

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**Witness/Auditor (Signature) Date**

[*If creating a child assent form:*]

For Child Assent:

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**Study Participant (Print Name)**

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**Witness/Auditor (Signature) Date**

For Parental Permission/Consent:

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**Study Participant (Print Name)**

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**Parent/Guardian (Print Name)**

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**Parent/Guardian (Signature) Date**