***Instructions:*** *Provide information in the sections below, replacing italicized directions/guidance (in this font color) with the appropriate information about your research protocol. If any sections do not apply to the research you will be conducting, delete those sections from the form.*

**SUBJECT CONSENT FORM FOR PARTICIPATION IN HUMAN RESEARCH AT MONTANA STATE UNIVERSITY**

*I am/we are* asking you to participate in a research study. This form is designed to give you information about this study. *I/We* will describe this study to you and answer any of your questions.

**Project Title:** *Provide the title of the study*

**Principal Investigator:** *Name*

 *Department*

 *Contact Information*

**Faculty Advisor** *(if PI is a student)***:** *Name*

*Department*

*Contact Information*

**What the study is about**

The purpose of this research is to….

*Provide a clear, concise explanation in lay language of the purposes of the research, including prominent use of the term "research." (Note: the IRB can waive this element if the study requires deception. In such cases, a debriefing statement should also be used to inform participants at an appropriate time after their involvement in the study.)*

**What we will ask you to do**

*I/We* will ask you to….

*Explain in simple, non-scientific language, what will be happening to the participant or what s/he will be asked to do during the study. Describe the participant's time commitment for each component. All procedures listed in the protocol should be described here, and experimental procedures (e.g., interventions, manipulations, treatments) should be specifically noted.*

**Risks and discomforts**

***In simple, non-scientific language, describe any reasonably foreseeable risks or discomforts:***

* ***Emotional risks (e.g., feelings of sadness or anxiety)***
* ***Social or economic risks (e.g., loss of confidentiality; effects to financial standing, employability, or insurability)***
* ***Physical risks (e.g., nausea, muscle aches, rashes, infection, discomforts, etc.)***
* ***Legal risks (e.g., any possibility of discovering activities that may require reporting to authorities, possibility of being arrested)***
* ***Other activities or procedures involved in the research that may carry risks (e.g., CAT or DEXA scans, x-rays, etc.)***

***If there are no known risks, state: I/We do not anticipate any risks from participating in this research.***

**Benefits**

***Describe the probable benefits of participation in the research. Be sure to distinguish between a likely direct benefit (e.g., from therapeutic or intervention research) and a possible indirect benefit (e.g., talking about/reflecting on an experience may lead to a better understanding of oneself). If there are no direct benefits to the participant, indicate that there are none.***

***Describe the expected benefits to society or scientific knowledge: e.g., “…information from this study may benefit other people now or in the future…” or “…we hope to learn more about \_\_\_\_\_\_\_ …”***

***Note: Compensation, l****earning about how experiments are conducted, receiving a gift, or earning extra credit for being a research participant* ***are not benefits and should not be listed here.***

**Payment for participation**

*Indicate whether the participant will receive compensation or payment for being in the study. If participants will not receive any compensation, state that there is no payment for taking part in the study.*

**Audio/Video Recording**

***If audio and/or video recording devices will be used, explain why the recordings are needed for the research and what will be done with them upon completion of the research (e.g., kept indefinitely, archived after transcription, destroyed after X years).***

***Provide a separate signature line on the consent form for the participant to be audio/video recorded, if the recording is optional for participation. For example:***

**Please sign below if you are willing to have this interview recorded *(specify audio or video)*. You may still participate in this study if you are not willing to have the interview recorded.**

* **I do not want to have this interview recorded.**
* **I am willing to have this interview recorded:**

**Signed:**

**Date:**

***If you plan to take photographs or make audio, video, or other types of recordings, and you want to use the photographs/record for activities beyond research analysis (e.g., in publications, presentations, or other promotional purposes), you will need to include a section that***

* ***Informs the participant that you are making a [type(s) of media used] recording in which the person’s name, likeness, image, and/or voice will be included;***
* ***Asks the participant to grant you the right*** *to make, use and publish Recordings in whole or in part in media forms now known (such as film, slides, and digital audio) or developed in the future. This includes the right to edit or duplicate any images/recordings;*
* ***Explains the limitations on reproduction, distribution, performance, or display of images/recordings;***
* ***Explains that the participant does not have rights to inspect or approve the finished product or printed/published matter that uses the images/recordings or versions of the images/recordings; and***
* ***Explains that the participant is will not receive any financial compensation for commercial and/or non-commercial (as appropriate) uses of the images/recordings.***

***The same signature line above may be used for this performance release information. The information provided may be altered, but you should contact the IRB office to verify it does not present any compliance or liability problems.***

**Use of Tissue Samples/DNA for Future Studies**

***For studies collecting biological specimens – blood, hair, DNA, etc. – where unused materials may be kept or extra materials may be collected for future research, include a separate section asking for consent to use the specimens. The following information should be included in this section:***

1. *A description of planned future use of the specimens. If this is unknown, state so.*
2. *An explanation as to whether you want to perform extra procedures (e.g., blood draws, biopsies, etc.) to collect these samples, or if you will store excess material from samples.*
3. *Details of procedures that will be used to protect the confidentiality and privacy of any personal identifiers that will be associated with the source of a tissue sample or cell line.*
4. *Information about the control and ownership of the tissue samples during storage.*
5. *The participant’s right to withdraw his/her consent at any time either by requesting that the tissue be destroyed or that all personal identifiers be removed. If the all identifiers are removed at time of storage (and no master list linking code numbers to identifiers will be maintained), this should be made clear so the participant will know you cannot identify their individual sample.*
6. *Information about the length of storage.*
7. *An indication whether the participant can obtain future access to the stored samples for information that may be of clinical relevance to him/her. Similarly, participants must be told if such information will not be available in the future (e.g., because personal identifiers are to be removed).*
8. *How you will handle future third-party access.*
9. *Information about possible secondary use of the stored tissue, or the possible creation of an immortalized cell line based on the specimen.*

*Also, a separate section needs to be provided for the participant to indicate if s/he consents to allow future use of their biological specimens. For example:*

**Do you give us permission to use your blood or tissue for future research?**

Please indicate if you agree to let us use your blood or tissue samples for future research. You do not have to give permission to use your blood or tissue samples for future research to participate in other parts of this study. Please ask questions if you do not understand why we are asking for your permission to use your samples for future research.

I agree to allow use of my blood or tissue sample for future research. *Please check Yes or No.*

* Yes – Please sign:
* No

**If you are injured by this research**

In the event that any research-related activities result in an injury, treatment will be made available including first aid, emergency treatment, and follow-up care as needed. Cost for such care will be billed in the ordinary manner to you or your insurance company. No reimbursement, compensation, or free medical care is offered by Montana State University. If you think that you have suffered a research-related injury, contact *[PI name]* right away at *[insert phone number]*.

**Privacy/Confidentiality**

*Explain how you will protect the participant’s privacy and/or confidentiality.*

*For research that involves Internet-based surveys…*

*…include the following statement:*

We anticipate that your participation in this survey presents no greater risk than everyday use of the Internet.

***OR***

*…include the following statement when using vendor not identified as accepted:*

Please note that the survey(s) [is/are] being conducted with the help of [company name], a company not affiliated with Montana State University and with its own privacy and security policies that you can find at its website. We anticipate that your participation in this survey presents no greater risk than everyday use of the Internet.

***When research activities or communication with participants will involve e-mail, include the following statement:***

Please note that email communication is neither private nor secure. Though [I am/we are] taking precautions to protect your privacy, you should be aware that information sent through e-mail could be read by a third party.

**Data Sharing**

*We strongly recommend that you include this section in your consent, to inform participants that you may share de-identified data you collect from them. Certain sponsors now require researchers to make available their de-identified data to the research community, as do a growing number of journals in a variety of disciplines. If you choose not to include the following language and later wish to share de-identified data, you may not be able to do so without re-contacting participants to obtain consent.*

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

**Future use of Identifiable Data or Specimens Collected in this Research**

***In addition to the recommended data sharing language, above, if you are collecting identifiable data or identifiable biospecimens, you must include one of the following:***

**Identifiers might be removed and the de-identified information or biospecimens used for future research without additional consent.**

**OR**

**Identifiable information might be used for future research with obtaining your consent.**

**OR**

**Your information or biospecimens will not be used or distributed for future research studies.**

**Information about use of your biospecimens**

***If you are collecting biospecimens, you must include the following:***

**Specimens collected from you for this study and/or information derived from your specimens *will/may/will not* be used to generate commercial profit. You will/will not share in any commercial value or other compensation from products developed using these specimens.**

***If clinically-relevant research results may be generated, you must include this statement:* You *will/will not* receive any clinically-relevant results discovered about you and/or the general subject population.**

***If your study may involve whole genome sequencing, you must include this statement:* This research may/will include whole genome sequencing.**

**Clinical Trial**

***If the IRB informs you that the study is a “clinical trial” include language such as the following, identifying the study as a clinical trial and stating that the study will be listed on ClinicalTrials.gov. For NIH-funded trials this is required; for all others this is strongly suggested:* This study is classified as a clinical trial and will be registered online at http://www.ClinicalTrials.gov. The website will not include any information that can identify you, but will include a summary of results once the research is completed. You can search this publicly-available website at any time.**

**Taking part is voluntary**

*Explain that the participant's involvement is voluntary, the participant may refuse to participate before the study begins, discontinue at any time, or skip any questions/procedures that may make him/her feel uncomfortable, with no penalty to him/her, and no effect on the compensation earned before withdrawing, or their academic standing, record, or relationship with the university or other organization or service that may be involved with the research.*

*If completing all research materials (e.g., answering all survey or interview questions; meeting a minimal requirement of entries in a weekly/monthly log) is required for participation, this should be fully explained instead.*

### Withdrawal by investigator, physician, or sponsor

The investigators, physicians or sponsors may stop the study or take you out of the study at any time should they judge that it is in your best interest to do so, if you experience a study-related injury, if you need additional or different medication/treatment, or if you do not comply with the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

**If you have questions**

***Explain how the participant can contact you if s/he has any questions or concerns. A standard statement in this section is as follows:***

The main researcher conducting this study is *[principal investigator’s name]*, a *[professor, graduate/undergraduate student, etc.]* at Montana State University. Please ask any questions you have now. If you have questions later, you may contact *[principal investigator’s name]* at *[email address]* or at *[phone number]*. If you have any questions or concerns regarding your rights as a subject in this study, you may contact the Institutional Review Board (IRB) for Human Participants at 406-994-4706 or access their website at <http://www.montana.edu/orc/irb/index.html>.

You will be given a copy of this form to keep for your records.

**Statement of Consent**

I have read the above information, and have received answers to any questions I asked. I consent to take part in the study.

Your Signature Date

Your Name (printed)

Signature of person obtaining consent Date

Printed name of person obtaining consent

This consent form will be kept by the researcher for at least five years beyond the end of the study.