Note (Remove this text before submitting):

Black text is information that needs to be entered. Red text includes instructions and should be deleted before submitting. Edit this document to accurately reflect your project and relevant IRB requirements. Consult the IRB Coordinator with any questions.

**University of Idaho**

**Research Study Consent Form**

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

**Researchers:** [List names, Credentials, Institutional Affiliation] NOTE: Students should not be listed as a PI and must list their faculty advisor in this role.

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

As of January 21, 2019 Federal Law requires that informed consent begin with a concise and focused presentation of key study information before being given other information. The goal is that this will assist potential subjects with understanding the reason why one might or might 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**

* A statement that the project is research and that participation is voluntary
* A brief summary of the study purpose
* Main study activities/procedures
* Reasonable, foreseeable risks or discomforts
* Duration of participation
* Reasonable, expected benefits
* Alternative procedures
* Funding sources
* Your data and biospecimens will be shared in a way where anybody around the world can gain access to them without review.

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

The purpose of the research is [describe the purpose of the study in simple terms]. You are being asked to participate because [state the main reason and/or eligibility criteria; e.g., age, gender, language, etc.] About # people will take part in this research.

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

* If you agree to take part in this study, you will be asked to [provide a detailed description of what the participant will be asked to do in chronological order (what, when, where, how) and what information about the participant will be obtained.] Taking part in the study will take about (include the time commitment for each step, the total amount of time involved, and how long the study will last). Indicate where the research will take place (note that additional privacy protections apply to data collected in the European Union or foreign countries). We will tell you about any new information that may affect your willingness to continue participation in this research. Data will be stored for a minimum of five years.

For research involving survey, questionnaires, and/or interviews:

* Describe questionnaires, surveys, and interviews and include examples of the most personal and sensitive questions you will ask.
* State that participants may refuse to answer any question that makes them uncomfortable and they can stop at any time.

If applicable:

* Add 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 participant will be able to review and delete portions. Explain if they will be altered to disguise identity, and if so, how.
* If your study involves deception, give as much information as possible.
* If more than one group, describe each group and how participants are assigned to a group.
* Add a statement about incidental findings.
* Add a statement about whether results will be returned to participants or their physician.

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

The potential benefits to you from being in this study include [describe only those that are likely for the research participants]. **OR** Although there is no direct or intended benefit from being in this study, you may help others in the future and sharing your data or biospecimens can contribute to future research. [insert details if appropriate].

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

The risks or discomforts of participating in this research include [include information on risks including physical, psychological, emotional, privacy, social or legal risks]. Describe the precautions that are being taken to minimize risks and steps that will be taken if risks occur.

We will do our best to protect your data and biospecimens during storage and
when they are shared. However, there remains a possibility that someone could identify
you. There is also the possibility that unauthorized people might access your data and biospecimens. In either case, we cannot reduce the risk to zero.

If applicable:

* Include risk of reporting illegal or reportable behavior (abuse, suicide or intent to harm).
* State if there are no funds available for compensation for study related injuries.
* Include risks associated with sensitive questions, for example, distress or discomfort.
* Provide referrals to counseling or other services.

**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:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information

The data for this study will also 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.

* Explain how you will maintain the participant’s privacy throughout the study.
* Describe where the data will be stored and how it will be protected.
* Describe who will have access to the data including research staff, IRB, Sponsors, agencies, or regulatory bodies (NIH, FDA, etc.)

[If applicable] We will be using [Zoom, Otter, other third-party software to record or transcribe identifiable data] to conduct the research. The Terms of Service and Privacy Policies for these can be found here: [include website locations here].

[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/confidential/identifiable.

This study is collecting data and biospecimens from you. We would like to make your data and biospecimens available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research.

These studies may be done by researchers at this institution or other institutions, including commercial entities. Our goal is to make more research possible. We plan to keep your data and biospecimens for a minimum of five years.

[Repository and Access information]

Your data and biospecimens may be shared with researchers around the world.
However, the decision to share your data and biospecimens is controlled by [indicate
which entity has control]. To get your data and biospecimens, future researchers must
seek approval from [indicate which entity has control]. The researchers must agree not
to try to identify you.

Option #1: If the data and biospecimens are coded and can be linked back to the
identity of the participant:
We will protect the confidentiality of your information to the extent possible. Your data
and biospecimens will be coded to protect your identity before they are shared with
other researchers. [indicate which entity has the code key] will have a code key that
can be used to link to your identifying information. The code key will be securely stored.

Option #2: If the data and biospecimens cannot be easily linked back to the identity of
the participant:
Your name and identifying information will be removed from any data and biospecimens
you provide before they are shared with other researchers. Researchers cannot easily
link your identifying information to the data and biospecimens.

Option #3: If the NIH has agreed that you should not share the data or biospecimens:

Your personal information and/or biospecimens collected during this study will not be used or distributed for future research studies even if the information is de-identified and cannot be linked back to you.

Consider cultural sensitivities around the return and/or destruction of biospecimens when research participants withdraw their consent for the storage and sharing of data and biospecimens.

If the data and biospecimens are being stored and shared for FDA-regulated research, adjust language to reflect that there are cases in which data and biospecimens may need to be maintained.

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).

If you do not agree to this, you may choose to not join the study.

**What if I no longer want to be in the study or I want to be in the study but not let researchers share my data or biospecimens**? [Researchers choosing the broad consent option #2 must have an approved plan in place with the IRB as to how consent/data/specimens will be tracked.]

Option #1 – For studies having a direct benefit to the participant. (Allowing optional sharing ensures the participant is not coerced into giving away their privacy to be in the study.)

It is your choice whether to let researchers share your data and biospecimens
for research in the future. If you say “yes,” you can change your mind later. If you say
“no,” you can still fully participate in this study because there may be a direct benefit to you from being in this study.

If you change your mind and no longer wish to have us store or share your data and
biospecimens, you should contact [insert contact info for PI]. We will do our best to honor your request and to retrieve any data and biospecimens that have been shared with other researchers. However, there may be times we cannot. For example, if we do not have a way to identify your data and biospecimens we will not be able to retrieve them.

In addition, if the data and biospecimens have already been used for new research, the
information from that research may still be used. We will [fill in what will happen to the
biospecimens after they are retrieved] any biospecimens we have or are able to
retrieve.

Please initial next to your choice:
\_\_\_\_\_\_YES, use my data and biospecimens in other research studies
\_\_\_\_\_\_NO, do NOT use my data and biospecimens in other research studies

Option 2: When sharing of data and biospecimens will not be optional (e.g., where
sharing is integral to the purpose of the study and there is not a direct benefit to the participant):

Participating in this study means you agree to share your data and biospecimens. You
can change your mind later, but researchers might still use your data and biospecimens
if they have already been shared. If you do not want your data and biospecimens used
for other projects, you should not participate in this study.

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

There will be no costs associated with participation in this research study. [or] Identify any anticipated costs and who is responsible for these costs.

Address whether or not participants will be compensated for participation. Indicate if partial payments will be included and schedule of each payment.

You will not receive payment or any other form of compensation for taking part in this study.

[or]

You will receive \_\_\_\_\_\_ for taking part in this study. [If payment is via gift card, specify the type of card. If it is entry into a lottery then indicate number of items available and estimated odds of winning] If you decide to quit the study you will receive \_\_\_\_\_. [Specifically explain the method or schedule for each payment.]

If compensating a value of over $50 then add the following information:

The University requires tracking of compensation for tax reporting purposes. You may be asked to provide personal information for payment purposes but this information will be stored confidentially and separate from research data.

The use of your data and biospecimens may lead to new tests, drugs, devices, or other
products or services with commercial value. These products or services could be
patented and licensed. There are no plans to provide any payment to you should this
occur.

**Who can answer questions about this research?**

If you have questions about this study or the information in this form, please contact the research team at: [Insert name, mailing address, e-mail address, and phone number] 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 University of Idaho Institutional Review Board at (208) 885-6340, or e-mail irb@uidaho.edu, or regular mail at: 875 Perimeter Drive MS 3010, Moscow, ID 83844-3010.

The University of Idaho Institutional Review Board has approved this project.

**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. 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 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.

If using audio/video/photography include the following:

As described above, you will be [audio/video recorded and or/photographed] as part of the research procedures. [Recordings/photographs] will be used for [data analysis only/ included in conference presentations/ used for educational purposes, etc.].

\_\_\_\_ I agree to the use of [audio/video recording or photography]

Add an option to request permission to identify an individual or other specifications if applicable.

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Signature of Participant Date

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

Printed Name of Participant

**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.

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

Signature of Person Obtaining Consent Date

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

Printed Name of Person Obtaining Consent