CONSENT FORM TEMPLATE

Institutional Review Board
601 S. Howes Street, Suite #208; Fort Collins, CO 80524
(970) 491-1553
CSU_IRB@colostate.edu | https://www.research.colostate.edu/ricro/irb/

The purpose of this template is to assist investigators and research personnel in creating consent documents for minimal risk research and, where possible, to facilitate consistency across research protocols.

Sections of this document include instructions to provide the user with a general overview of information required in the section. The instructions and optional text are in blue and required text is in black. These instructions and the sample language are not intended to be comprehensive. Investigators are encouraged to modify the template language whenever appropriate to increase the potential for subject comprehension and relevance to a specific study. Use of the headings is strongly recommended.

DELETE THIS PAGE, ALL INSTRUCTIONS (BLUE TEXT), AND ANY NON-APPLICABLE SECTIONS BEFORE SUBMITTING THIS FORM TO THE IRB OFFICE.

Tips for writing consent forms:

- Informed consent is a process, not just a form. Information must be presented that will enable potential participants to voluntarily decide whether to enroll in the study. Informed consent is a fundamental mechanism to ensure respect for persons through provision of thoughtful consent for a voluntary act. The procedures used in obtaining informed consent should be designed to educate the subject population in terms that they can understand. Therefore, consent documents must be written in plain language with as few technical terms as possible.
- Shorter documents result in greater comprehension of the content. Therefore, consent documents should be limited to required elements and presented in a way that highlights key information. Non-essential information should be omitted or captured in a supplemental document.
- The consent document should be written at a level comprehensible to your target population. If your study targets the general public, the ideal consent form would be written at or below an 8th grade reading level, with a readability score of more than 50 (the higher the score, the easier your document is to read). Use Flesch-Kincaid to test the readability level of your document. See Microsoft Office Support and Informed Consent for more information.
- Use of illustrations, diagrams, color, and supplemental materials are encouraged when their use may enhance comprehension.
- Consider your population when finalizing your consent document's format and font size. For example, narrow margins and a font size of 10 would not be appropriate for an elderly population. Also consider using bullets to describe research activities.
- If enrolling children, make appropriate changes to section headings (e.g., replace "I" with "my child", etc.).
- Write directly to the reader, as though you are explaining the facts in person. Consent language should be written in the second person ("you"), not in the first person ("I"). Instead of "Participant's time commitment will be" state "Your time commitment will be…"
- Minimize passive voice to the extent possible. Example of passive voice: "A summary of results will be sent to all study participants." Example of active voice: "We will send you a summary of the results."
- Post-approval, if deficiencies are noted or when additional information will improve the consent process, remember to submit the revised consent forms to the IRB office for review and approval prior to use.

Insert PI's departmental letterhead here

ADULT PARTICIPANT INFORMED CONSENT

Department of Insert Department

Participant Study Title:

> ***Optional: If the formal study title is too long or includes technical terminology, you may consider creating a brief title that participants will better understand. If you select to do this, the Formal Study Title will not be included in this template.***

Formal Study Title:

> ***List the title in this section exactly as it appears on the IRB Application.***

PRINCIPAL INVESTIGATOR: Faculty Investigator, Degree, and Rank.

CO-INVESTIGATOR(S): XXX (Delete if Not Applicable)

STUDENT INVESTIGATOR(S): xxx (Delete if Not Applicable)

SPONSOR: xxx (Delete if Not Applicable)

WHAT IF I HAVE QUESTIONS?

For questions or concerns about the study, you may contact **NAME** at **PHONE NUMBER.** For questions regarding the rights of research subjects, any complaints or comments regarding the manner in which the study is being conducted, contact the CSU Institutional Review Board at: CSU_IRB@colostate.edu; 970-491-1553.

WHAT IS THE PURPOSE OF THIS STUDY?

Describe, at the 6th-8th grade reading level, the purpose of the study.

The purpose of this research study is to xxx.

WHY AM I BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being asked to participate in the study because you fit these criteria: xxx.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST? Describe, at the 6th-8th grade reading level, how long the participant's time commitment will be and

where the study will take place. If there are several activities, detail the time commitment for each activity. **Note: This is information specifically for the participant, not the length of your data collection for the entire study.**

WHAT WILL I BE ASKED TO DO?

If you volunteer to participate in this study, you will be asked to do the following: Describe at the 6th-8th grade reading level what the participant will do as part of your study. Avoid using jargon. If your participant is being asked to participate in multiple activities, it may increase comprehension to use bullets to describe the activities.

ARE THERE ANY BENEFITS FROM TAKING PART IN THIS STUDY? *(List direct benefits to subjects, if any. If none, state. If appropriate, list the broader societal benefits briefly (e.g. "There may be no direct benefit to you as a participant in this study, but we hope to learn more about [topic] and may help [future populations with a similar issues/future researchers design interventions to help with a topic] etc. This section must be consistent with the benefits as explained in the protocol submitted to the IRB.)*

There may be no direct benefit to you as a participant in this study. However, we hope to learn more about xxx.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS? *(Risks must be explained, including the likelihood of the risk. This section must be consistent with the risks as explained in the protocol submitted to the IRB. If none, state. Keep in mind that loss of confidentiality is almost always a risk in research. If physical injuries or mental health risks are present, a sentence must be included that states whether treatment or resources will be provided from the research team or from the research team's resources.)*

There are no known risks included with this study. While the level of risk is minimal, you may become uncomfortable with some questions related to xxx.

WILL I RECEIVE ANY COMPENSATION FOR TAKING PART IN THIS STUDY? *(If subjects receive class points, remuneration for their time commitment, or token as a thank you, include that information here. Explain when disbursement will occur and conditions of payment. For example, if monetary benefits will be prorated due to early withdraw. Note here if there will be no compensation. Remember that compensation is not considered a benefit.) You will/will not be compensated for participating in this research.*

WHO WILL SEE THE INFORMATION THAT I GIVE? *Edit the section below as appropriate for the particular study. Bracketed text must be modified as appropriate or deleted as applicable:*

All information gathered in this study will be kept as confidential as possible. Your privacy is very important to us and the researchers will take every measure to protect it. Your information may be given out if required by law; however, the researchers will do their best to make sure that any information that is released will not identify you. No reference will be made in written or oral materials that could link you to this study. For this study, we will assign a code to your data so that the only place your name will appear in our records is on the consent

and in our data spreadsheet which links you to your code. Only the research team will have access to the link between you, your code, and your data. All records will be stored in [a restricted access folder; an encrypted, cloud-based storage system; a locked drawer in a restricted-access office] at CSU for three years after completion of the study. After the storage time, the information gathered will be destroyed. We may be asked to share the research files with the sponsor or the CSU Institutional Review Board ethics committee for auditing purposes. If compensation is provided, include: Your identity/record of receiving compensation (NOT your data) may be made available to CSU officials for financial audits.

If research includes focus group data collection portion. Delete if not:
Participation in a focus group involves some loss of privacy. The researchers will make every effort to ensure that information about you remains confidential but cannot guarantee total confidentiality. Your identity will not be revealed in any publications, presentations, or reports resulting from this research study. *Include the following bracketed text if your research is in a group setting:* [While we will ask all group members to keep the information, they hear in this group confidential, we cannot guarantee that everyone will do so.]

If research includes an online survey or online data collection portion. Delete if not:
The research team works to ensure confidentiality to the degree permitted by technology. It is possible, although unlikely, that unauthorized individuals could gain access to your responses because you are responding online. However, your participation in this online survey involves risks similar to a person's everyday use of the internet.

Mandatory Report – If Applicable. Delete if not:
You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court OR *to tell authorities if we believe you have abused a child, or you pose a danger to yourself or someone else.*

HIPAA AUTHORIZATION *Edit the section below as appropriate for the particular study. If not applicable, delete this section.*
Federal regulations give you certain rights related to your health information. These include the right to know who will receive the information and how it will be used. The Principal Investigator must obtain your authorization (permission) to use or release any health information that might identify you.

What information may be used and shared?
The Principal Investigator and study staff will use and share your health information as part of this research study. This may include your name, address, telephone number or other facts that could identify the health information as yours.

Examples of the information that may be used are:

- Medical records
- Information created or collected during the research. This could include your medical history, and dates or results from any physical exams, laboratory tests or other tests.

Who will receive information about you?
The study staff may share your personal health information with:
- the funding agency, including persons or companies working for or with the funding agency
- Colorado State Institutional Review Board
- U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- other regulatory agencies responsible for oversight of the conduct of the research

Why will this information be used and/or given to others?
The Principal Investigator, Research Study team, funding agency, and the groups listed in the section above may use your health information:
- to complete this research
- to evaluate the results of the study
- to check that the study is being done properly
- to obtain marketing approval for new products resulting from this research

Is my health information protected after it has been given to others?
Your health information may be further shared by the groups above. If shared by them, the information may no longer be covered by this Authorization and may be released without your permission.

What if I decide not to allow the use of my health information?
You do not have to sign this form. If you do not sign this form, you cannot take part in this research study.

May I withdraw or revoke (cancel) my permission?
YES. You may withdraw your permission to use and disclose your health information at any time. You can do this by sending written notice to the Principal Investigator. If you withdraw your permission, you will not be able to continue being in the research study.

What happens if I want to withdraw my authorization?
Information that has already been gathered may still be used and given to others. If you withdraw your permission, no new health information will be gathered unless you have a side effect related to the study.
If you withdraw from the study but do not withdraw your Authorization, new health information may be collected until this study ends.

Will my authorization expire?
This Authorization does not expire unless you withdraw it in writing before then.

May I review or copy the information obtained or created about me?

YES. You have the right to review and copy your health information. However, your access to this information may be delayed until the study is complete.
Your decision to withdraw your Authorization or not to participate will not involve any penalty or loss of access to treatment or other benefits to which you are entitled.

DO I HAVE TO TAKE PART IN THE STUDY?

Your participation in this study is voluntary. You may refuse to participate in this study or in any part of this study. You may withdraw at any time without prejudice to your relations with CSU. You are encouraged to ask questions about this study at the beginning or any time during the research study.

Future uses in the consent form can be accommodated by including ONE of the following statements:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Participant Consent:

Your signature acknowledges that you have read the information stated and voluntarily wish to participate in this research. Your signature also acknowledges that you have received, on the date signed, a copy of this document containing __ pages.

_____*X*_____ _____
Signature of participant Date

_____Robert R_____
Name of participant

_____ _____
Signature of person providing information Date

_____
Name of person providing information