The purpose of this template is to assist investigators and research personnel in creating consent documents for 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 blueand required text is in black. These instructions and the sample language are not comprehensive. Use of the headings recommended.

**PLEASE USE TRACKED CHANGES AND DELETE THIS PAGE, ALL INSTRUCTIONS IN 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](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116) 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](https://support.office.com/en-us/article/Test-your-document-s-readability-0adc0e9a-b3fb-4bde-85f4-c9e88926c6aa) and [Informed Consent](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html) for more information.
* Use of illustrations, diagrams, color, and supplemental materials is 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.

**ADULT PARTICIPANT INFORMED CONSENT**

***List the title in this section exactly as it appears on the IRB Application/Grant/Proposal***

#

#  PRINCIPAL INVESTIGATOR: Faculty Investigator, Degree and Rank, Department, Contact information.

**CO-INVESTIGATOR(S): XXX**

**STUDENT INVESTIGATOR(S)**:

 **SPONSOR: xxx**

**CONCISE STATEMENT OF STUDY**

#  *If the consent form is greater than four (4) pages written, please include a concise statement.*

This research study is aimed answer [what]. You may be interested because you are [eligibility criteria]. This research study will take [how long]. There are [minimal risks or some risks] to participating in this study, like [list common risks. We hope that this research will benefit [list the benefit of the research]. You can find more details on this study following in the body of this consent form. If you are interested in continued discussion about presentation, we would like to discuss more with you through this consent presentation.

**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: change to invited to take part 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 take part 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 the participant is being asked to take part in multiple activities, it may help 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 given 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, in order of most to least likely. This section must be consistent with the risks as explained in the protocol given 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.)*

While the level of risk is minimal, you may become uncomfortable with some questions or procedures related to xxx.

*Some commonly used activities and their IRB approved boilerplate risks:*

Body Composition (DEXA) Scan – The risks associated with the DEXA are very low. The maximum radiation dose you will receive in this study is less than 1/1000th of the federal and state occupational whole body dose limit allowed to radiation workers (5,000 mrem). Put another way, the largest dose from any scan we utilize with this DEXA ranges from 1.2 mrem (Whole body scan) to 12.2 mrem (for several of the regional scans, such as lumbar, femur, and forearm scans). The average annual background radiation you already receive is at least 620 mrem/year. The more radiation you receive over the course of your life, the more the risk increases of developing a fatal cancer or inducing changes in genes. The radiation in this scan is not expected to significantly increase these risks, but the exact increase in such risks is not known. There are no discomforts associated with this procedure. Women who are or could be pregnant should receive no unnecessary radiation and should not take part in this study.

Maximal Oxygen Consumption Test on Cycle Ergometer – There is a risk of fatigue (temporary muscle tiredness), muscle strain, heartbeat abnormalities (arrhythmias), a 0.01% chance of death (in people who have heart problems), a 0.02% risk of cardiac arrhythmias that would require you to go to a hospital (in people who have heart problems), and a risk of an increase or decrease in blood pressure.

PET Scan and Radiation Dose - As part of this study we will perform a PET/CT scan of your upper body (except head) by using a radioactive tracer. We will first inject the tracer. Then we will look at the area through a scanner. The radioactive tracer is estimated to give you a dose of ~ 215 mrem, roughly equivalent to half of one year’s natural background radiation dose. This is an estimate - the amount of radiation dose you receive could be higher or lower, depending on how much tracer is injected into your body, and your body size in relation to the dose. The radioactive drug is eliminated from the body quickly and should be gone from your body within 24 hours. Most of the drug will be eliminated through urination. Although the FDA has approved the PET scan device for diagnostic purposes, the PET scan being done in this study is for research purposes only. If any abnormal findings are found during the PET scan the study doctor will recommend that you contact your primary care physician for follow-up.

CT Scan and Radiation Dose - As part of this study we will perform a CT scan (Computed Tomography) of your body. CT is a way of taking detailed pictures inside your body by using X-rays. X-rays are a type of radiation. The instrument produces cross-sectional images of the body. Using the CT information combined with the PET radiotracer, we are able to construct 3 dimensional images of your body allowing for this research to be conducted. The amount of radiation dose received during a CT procedure is substantially higher than the DEXA or PET procedures. The CT scan for this particular study has been estimated to be 2,030 mrem (2.03 rem). This is slightly more than 4 times your annual background radiation dose in Colorado. While the dose is much higher for a CT scan, it is interesting to note that it is below the occupational radiation worker limits as defined by State of Colorado Regulations (5 rem per year).

**WHAT SHOULD I DO IF I BECOME INJURED?**

*(This section is required for research that involves greater than minimal risk to participants)*

If you are injured because of participation in this study, please contact the Principal Investigator at the number listed in the “Who to contact” section of this form. The Colorado Governmental Immunity Act determines and may limit Colorado State University's legal responsibility if an injury happens because of this study. Should you need medical aid, you or your health insurance will be responsible for the costs.

**WILL I RECEIVE ANY COMPENSATION FOR TAKING PART IN THIS STUDY?**

*(If subjects receive class points, payment 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 are prorated due to early withdraw. Note here if there will be no compensation. Remember that compensation is not a benefit.) You will/will not be compensated for taking part 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 members of 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.

There are organizations that may inspect research records that may include yours. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

* The study sponsor and any drug company supporting the study *(Delete sponsor and/or drug company if not applicable).*
* For funded studies, the CSU financial management team may request an audit of research expenditure, in which only your participation in the research may be shared, but not your research data.
* The Colorado State Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
* Office of Human Research Protections, the Food and Drug Administration, and similar ones if other countries are involved in the study.

If compensation is provided, include: Your identity/record of receiving compensation (NOT your data) may be made available to CSU officials for financial audits. Your identity/record of receiving compensation (NOT your data) may be made available to CSU officials for financial audits.

*If NIH funded, Certificate of Confidentiality language:*

National Institutes of Health (NIH) has additional protections for research they fund. Namely, they consider your data to be protected under a “Certificate of Confidentiality."  This Certificate gives added protection for your privacy even if the records are subpoenaed.  We will not give information to anyone unless you provide a signed release telling us to do so, or unless we have reason to suspect: 1) abuse, neglect, or endangerment of a child or elder; 2) or that anyone is in immediate danger of seriously hurting himself/herself or someone else. In these situations, we may have to make a report to the appropriate authorities.

If the U. S. Department of Health and Human Services (DHHS) audits our research project, they can have access to information about you.  However, they cannot report it to the police or use it for any reason besides the audit.  Even though a Confidentiality Certificate was issued, it does not mean that the Secretary of DHHS supports this research project.

*If your study will be listed on* [*http://www.ClinicalTrials.gov*](http://www.ClinicalTrials.gov) *, the consent form must include this statement:*

“A description of this clinical trial will be available on <http://www.ClincialTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.”

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**HIPAA AUTHORIZATION** ***(Include this section if your research involves the use of PHI or identifiable information originating from medical records)***

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. You can decide not to sign the form and not to participate in the 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.

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*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:*

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.

**WILL MY DATA BE USED FOR FUTURE RESEARCH?**

Option (i): If you choose to take part in this study, your private [information/biospecimen] will be collected. Any identifiers linking you to your private [information/biospecimen] will be removed. After we remove those identifiers, the [information or biospecimen] could be used for future studies or distributed to another research for future research studies without your permission.

OR

Option (ii): If you choose to take part in this study your private [information or biospecimen] collected for this study will not be used or distributed for future studies, even if we remove all identifiers linking you to your [information or biospecimen].

**MANDATORY REPORTING** – *(if your study involves interventions with children or families this section may apply)*

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.*

**CAN MY PARTICPATION IN THE STUDY END EARLY?**

*Edit the section below as appropriate for the particular study. Bracketed text must be modified as appropriate or deleted as applicable:*

There are a number of reasons your participation could end early:

[Please provide a list of anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject’s consent (e.g., if you do not agree to intervention or are unable to complete procedures and/or answer questions, if your health status changes significantly/ you no longer meet the inclusion/exclusion criteria, if you repeatedly miss scheduled appointments, etc.)]

If your participation ends early for any of the above reasons, we will contact you and let you know the reason why you will not be allowed to continue. [If applicable] We will make arrangements to send you the study results you have completed. [If applicable] Should our testing reveal information that suggests you need to be referred for medical care, we will refer you to your primary care physician. [If applicable] You will receive monetary compensation only for those portions of the study that you complete.

**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.

**WHO TO CONTACT**

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.

# 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 informed consent document containing \_\_ pages.

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

Signature of participant Date

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Name of participant

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

Signature of person obtaining informed consent Date

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Name of person obtaining informed consent