The purpose of this template is to assist investigators and research personnel in creating informed consent documents and to facilitate consistency and accuracy of informed consent language across research protocols.

Sections of this document include brief 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 relevancy to a specific study.* Use of the headings is strongly recommended, but subheadings need only be used if they will increase readability of the form.

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

**Tips for writing consent forms:**

* Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as research subjects. 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, informed consent language and its documentation must be written in plain language. Plain language is simple and has as few technical terms as possible so that the intended audience can understand it from a single reading.
* Use of illustrations, diagrams, color, and supplemental materials are encouraged when their use may enhance comprehension.
* 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 <http://office.microsoft.com/en-us/help/HP101485061033.aspx>
* If enrolling children, make appropriate changes to section headings (e.g., replace “I” with “my child”, etc.).
* The written presentation of information is used to document the basis for consent and for the subjects' future reference. Revised consent forms should be submitted to the IRB for review when deficiencies are noted or when additional information will improve the consent process.
* 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”).
* 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.”

Consent form

**Project Title:**  Title

**Principal Investigator:** Name of individual responsible for the study

**Student Researcher:** Name of student if project is for a thesis or dissertation

**Co-Investigator(s):** Name of additional individuals associated with the study

**Sponsor:** Indicate internal and/or external funding entity

**Version Date:** Indicate current date. Change date if consent form is revised.

### WHAT IS THE PURPOSE OF THIS FORM?

This form contains information you will need to help you decide whether to be in this research study or not. Please read the form carefully and ask the study team member(s) questions about anything that is not clear.

# WHY IS THIS RESEARCH STUDY BEING DONE?

The purpose of this research study is to {briefly describe the purpose of the study}.

If the study is being conducted by a student for the completion of a thesis or dissertation, please indicate that here.

 Up to {insert target enrollment number} may be invited to take part in this study.

### WHY AM I BEING INVITED TO TAKE PART IN THIS STUDY?

You are being invited to take part in this study because {insert brief description of study population}.

1. **What will happen if I take part in this research study?**

Make clear that the activity involves research and describe the overall experience that will be encountered. Explain the procedures, including any parts that are experimental.

The study activities include VO2max testing. This is an exercise test that progresses from low to high intensity to measure the maximal rate at which your body can use oxygen during physical activity.

{Include all study activities (e.g. surveys, questionnaires, interviews, randomization, observation, description of study arms, etc.)}.

Study duration: Insert the expected length of time it will take for study visits or scheduled procedures, as well as the total expected length of participation (e.g. the interview will take about one hour; you will be asked to visit the lab three times and each visit will take about two hours). Avoid references to specific dates in case your study does not begin or end on schedule.

**ADDITIONAL SECTIONS TO BE USED WHEN APPLICABLE**

**Recordings and photographs:** Indicate whether tape recordings or videotapes will be made or whether photographs will be taken. If recording is a required study activity, explain that they should not enroll if they do not wish to be recorded. If recordings are an optional part of the data collection, include the separate section for the participant’s initials here.

\_\_\_\_\_\_I agree to be {audio recorded, video recorded, and/or photographed}.

*Initials*

\_\_\_\_\_\_I do not agree to be {audio recorded, video recorded, and/or photographed}.

*Initials*

**Complex schedule of study visits:**  If the study involves a complex schedule, you may insert a simplified chart or calendar here to supplement the narrative.

**Placebo:** We may give you a placebo during this study. A placebo is a neutral ingredient.

**Randomization:** This study involves a process called randomization. Randomization means that you are put into one of the groups by chance. It is like flipping a coin {modify if more than two groups (e.g., like drawing names from a hat.}. Neither you nor the people doing the study will choose what group you will be in. You will have a {insert chance – equal, one in three, etc.} chance of being placed in any group.

**Blood draws:** We will draw about {insert teaspoons/tablespoons and cc} of blood by putting a needle into a vein in your arm. This is the standard method used to obtain blood for tests. If more than one draw will occur insert the following sentence: We will take a total of {insert teaspoons/tablespoons and cc} of blood over the course of this study.

**Significant new findings**: If applicable, insert a statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.

**Storage and Future use of data or samples:** If you plan to store samples, explain how long they will be retained (i.e., indefinitely, five years, destroyed when the study is completed), how they will be stored (i.e., with or without identifiers), what they will be used for, and whether subject permission will be sought for future studies.

Sample language for biological samples: We may store your {blood, urine, saliva, etc.} sample indefinitely. Because it is not possible for us to know what studies may be a part of our future work, we ask that you give permission now for us to use your sample without being contacted about each future study. Future use of your sample will be limited to studies about {insert appropriate disease, condition, or specific field of study}. We will not pay you for the use of your sample or any products, patents, or licenses that result from these samples. If you agree now to future use of your samples, but decide in the future that you would like to have them removed from research tests, please contact {name and contact information for PI}.

Sample language for data: Because it is not possible for us to know what studies may be a part of our future work, we ask that you give permission now for us to use your personal information without being contacted about each future study. Future use of your information will be limited to studies about {insert appropriate disease, condition, or specific field of study}. If you agree now to future use of your personal information, but decide in the future that you would like to have your personal information removed from the research database, please contact {name and contact information for PI}. If identifiable information will be destroyed prior to the destruction of the data, insert the following statement: We will be destroying all identifying information {insert timeline for destruction of identifiers}. Once the identifying information is destroyed, we will not be able to remove your information from the larger dataset.

If other investigators, institutions or groups may have access to the individual’s personal information, this possibility should be described. If subjects can participate in the study without giving permission for future use of personal information, add opt-in/opt-out section for the subject to indicate whether permission is being given.

\_\_\_\_\_\_You may store my {information and/or samples} for use in future studies.

*Initials*

\_\_\_\_\_\_ You may not store my {information and/or samples} for use in future studies.

*Initials*

**Future contact:** We may contact you in the future for another similar study. You may ask us to stop contacting you at any time.

**Study Results:** Explain whether and how study results will be shared with subjects.

### WHAT ARE THE RISKS AND POSSIBLE DISCOMFORTS OF THIS STUDY?

The possible risks and/or discomforts associated with the being in the study include:

All reasonably foreseeable risks, discomforts, inconveniences, and harms that are associated with the research activity should be described. Investigators should be forthcoming about risks and not understate reasonably foreseeable risks. If additional risks are identified during the course of the research, the consent process and documentation will require revisions, and subjects who previously consented may need to be re-contacted and informed of the additional risks.

Describe any potential risks – including the potential for psychological or physical harm or discomfort, as well as legal or privacy related issues. If you are collecting individually identifiable information (such as names or birthdates), a potential for breach of confidentiality exists. In this case, you may use the suggested sentence under “additional sections” below.

**Do not include evaluative statements about the risks, such as, “Risks are minimal.”**

Depending on the type of study, some risks may be better described as things that could make the participant “uncomfortable” – such as fatigue or embarrassment. If there are no known risks, state that there are no foreseeable risks to participating.

Include procedures that will be followed to minimize identified risks.

**Please see the IRB website for suggested language for common risks.**

**Risks of VO2max Testing:**

* + Acute exercise may present a risk of sudden death
	+ Cardiovascular event (i.e., heart attack or cardiac arrhythmia)
* Overall risk of cardiac events is about 6 events per 10,000 tests
	+ Serious injury
	+ Falling
	+ Physical discomfort from the test and equipment
	+ Fatigue
	+ Muscle aches, cramps, joint pain
	+ Muscle strain and/or joint injury
	+ Delayed muscle soreness
	+ Abnormal blood pressure/heart rate
	+ Shortness of breath
	+ Lightheadedness, fainting
	+ Dizziness
	+ Nausea
1. **what happens if i am injured?**

Delete section if no potential for physical injury or mental/emotional harm exists.

Oregon State University has no program to pay for research-related injuries. If you think that you have been injured as a result of being in this study, {insert description or plan or process that may be followed. If research-related injury (i.e., physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk, an explanation must be given as to whether any compensation and treatment will be provided to an injured subject. If so, the compensation and treatment should be described, or the subject should be told where further information may be obtained. The regulations prohibit requiring subjects to waive or appear to waive any of their legal rights. Subjects should never be made to believe they are waiving their rights.}

### WHAT ARE THE BENEFITS OF THIS STUDY?

Any benefits to subjects or others that may reasonably be expected from the research should be described. Investigators should be frank about benefits and not overestimate or magnify the possibility of benefit to the subject. If there is no reasonable expectation of benefit, the subject should be told this. Payment to subjects should not be listed or described as a benefit of participating in the research.

Use if direct benefit to participants is anticipated:

We do not know if you will benefit from being in this study. However, you may {insert anticipated benefit}

Use if no direct benefit to participants is anticipated:

This study is not designed to benefit you directly.

### WILL I BE PAID FOR BEING IN THIS STUDY?

You {will / will not} be paid for being in this research study. {Clearly describe the monetary compensation (total amount, average total amount, amount per visit, amount per hour, etc.). If compensation is pro-rated when a participant withdraws prior to completing the study, explain how it is pro-rated. If participants must complete the study activities in order to receive compensation, please state. Describe any non-monetary compensation (e.g., extra credit, gift certificate), separately from monetary compensation and include the approximate value when appropriate.

Compensation offered in the form of checks and compensation greater than or equal to $600 paid within one calendar year, requires the collection of identifying information for the purposes of tax reporting. In these cases, the consent document must inform subjects that they will be asked to provide their Social Security Number or Individual Tax Identification Number to receive payment. In the event that the target population is known not to possess such identification, a flat tax may be withheld from payments large enough to require reporting to the Internal Revenue Service (IRS). If this is the approach to be taken by the PI, the consent document should include a brief statement indicating that taxes will be withheld from the study payment and an estimate of the net amount subjects should anticipate.

**Raffles and lotteries** are permitted in some circumstances. Please see the policy on the IRB website for additional information.

Sample Language: Everyone who enrolls in this study will be given/paid \_\_\_\_\_.We will also enter your \_\_\_\_(name, code, ticket number, etc.) into a drawing for \_\_\_\_ (prize, dollar amount). The chance of winning is about \_\_\_ in \_\_\_ (i.e. 1 in 100). There is no guarantee that you will win a prize. We can enter you into the drawing even if you choose not to be in the study or if you choose not to finish the activities.

### WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

### Delete section if no costs to the subjects are anticipated.

Insert any costs to the participants for which they will not be compensated or procedures that will be billed to their insurance (e.g. lab tests, treatment at an outside facility, parking, lost, damaged, or unreturned study equipment, etc.).

### WHO IS PAYING FOR THIS STUDY?

Delete this section if study is unfunded.

{Insert name of sponsor} is paying for this research to be done.

### DOES ANY MEMBER OF THE STUDY TEAM HAVE A CONFLICTING INTEREST?

Delete this section if no potential conflict of interest exists.

A conflict of interest occurs when a researcher or the University has a financial or other business interest that could affect the research. In some situations, the results of a study might lead to a financial gain for the investigator(s) and/or the University.

Insert one of the following statements followed by a brief description of the potential conflict:

* One or more of the investigators working on this study has a potential conflict of interest.
* Oregon State University has a potential conflict of interest.
* One or more of the investigators working on this study and Oregon State University have a potential conflict of interest.

If you have questions or concerns about this, please contact the Institutional Review Board Office at (541) 737-8008.

### WHO WILL SEE THE INFORMATION I GIVE?

The information you provide during this research study will be kept confidential to the extent permitted by law. Research records will be stored securely and only researchers will have access to the records. Federal regulatory agencies and the Oregon State University Institutional Review Board (a committee that reviews and approves research studies) may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

If the results of this project are published your identity will not be made public. {Omit this statement if the identity of the subjects may be readily ascertained. Please note that subjects may be indirectly identifiable if, for example, direct quotes are used, the organization the person is affiliated with is named, or the subject population is part of a small or well-defined group.}

If study is funded, include sponsor as an entity that may see the information.

If the research is supported by federal funding, indicate how you will meet the federal data sharing requirements.

If tape recordings or videotapes are made, explain who will have access, if they will be used for education purposes, and when they will be erased.

To help ensure confidentiality, we will {describe the methods you will use to help ensure confidentiality, e.g., using identification code numbers on data forms instead of names, having locked filing cabinets and storage areas, using password-protected computer files.}

If the study is a clinical trial and will be posted to ClinicalTrials.gov, the following sentence must be included verbatim: A description of this clinical trial will be available on [*http://www.ClinicalTrials.gov*](http://www.ClinicalTrials.gov/), as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**ADDITIONAL SECTIONS TO BE USED WHEN APPLICABLE**

If data sets, presentations, or publications will be stored in University Archive or Scholars Archive, provide details of the information that will be stored.

**Certificate of Confidentiality**: When a researcher obtains a Certificate of Confidentiality, the subjects must be told about protections afforded by the Certificate and any exceptions to those protections - i.e., the circumstances in which the investigators plan to disclose, voluntarily, identifying information about research participants (e.g., child abuse, harm to self or others, etc.). This information should be included in the consent form. The researchers should eliminate provisions in the consent form template that may be inconsistent with the Certificate protections (such as references to disclosures required by law, since the Certificate enables researchers to resist disclosures that would otherwise be compelled by law). Researchers may not represent the Certificate as an endorsement of the research project by the DHHS.

If your study involves highly sensitive information, and you have obtained, or plan to obtain a Certificate of Confidentiality, insert the following paragraph:

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health (NIH). Under some circumstances, this Certificate may help researchers to resist demands for information that would identify you. The Certificate cannot be used to resist a demand for information from the U.S. Government that is used for auditing or evaluation of federally funded projects.

**Studies which may reveal violence, abuse, neglect, or self-inflicted injury:**

Under Oregon law, researchers are required to report to the appropriate authorities any information concerning child abuse or neglect. The researchers may also report threats of harm to self or to others.

**Genetic Research:**

Sample language: Participation in this study may indicate that you are a carrier of the specific gene under study. The results of the genetic analysis performed for purposes of this research study will not appear in your medical record. We will not release information about you unless you authorize us to do so or unless we are required to do so by law. However, if you tell your family doctor about participating in this study, this information may then become part of your medical record. Insurance companies commonly have access to medical records.

A Federal law called the Genetic Information Nondiscrimination Act (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information.

This law does notprotect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. GINA also does not protect you against discrimination if you have already been diagnosed with the genetic condition being tested.

We will make every effort to protect your identity but there is a risk that information which identifies you could be accidentally disclosed.

Additional information which may be provided includes whether or not participants have the option of knowing the results of their genetic analysis, whether incidental findings will be shared with subjects, whether or not genetic counseling would be available and who would pay for such counseling.

**Recruiting from the Center for Healthy Aging Research (CHAR) LIFE Registry:** CHAR requires that researchers who recruit from the LIFE Registry provide them with a list of participants who were recruited from the Registry. If participants will be recruited from the Registry, please insert the following paragraph:

If we contacted you through the Center for Healthy Aging Research (CHAR) LIFE Registry, we will be providing CHAR with any updates to your contact information. We will also tell them whether or not you chose to participate in this research study.

1. **What other choices do I have if I do not take part in this study?**

Appropriate alternatives to participating in the research project that might be advantageous to the subject should be described.

Participation in this study is voluntary. If you decide to participate, you are free to withdraw at any time without penalty. You will not be treated differently if you decide to stop taking part in the study. If you choose to withdraw from this project before it ends, the researchers may keep information collected about you and this information may be included in study reports.

**ADDITIONAL SECTIONS TO BE USED WHEN APPLICABLE**

**Required vs Optional questions:** If the study involves interviews, surveys, or questionnaires, with optional questions, include a statement that the participant is free to skip any questions that he/she would prefer not to answer. If answering all questions is required, clearly state that while study participation is voluntary, all questions must be answered in order for their individual responses to be included in the study results.

**Participation terminated by investigator:** If there are any circumstances under which a subject's participation may be terminated by the investigator without regard to the subject's consent, please describe them here (e.g., subject does not come in for critical visits or does not follow instructions for study activities, etc.

**Research during class time:** If study activities take place during class time, explain what participants will do during that time if they choose not to participate.

**Prisoners:** Choosing to take part or choosing not to take part in this study will not impact the length of your sentence, your parole, or any other aspect of your incarceration.

**Students:** If students will be enrolled, insert the following statement: Your decision to take part or not take part in this study will not affect your grades, your relationship with your professors, or standing in the University.

**Employees:** Your decision to take part or not take part in this study will not affect your job.

**When the researchers have a pre-existing relationship with potential participants:** Your decision to take part or not take part in this study will not affect your relationship with the researcher.

### WHO DO I CONTACT IF I HAVE QUESTIONS?

If you have any questions about this research project, please contact: {insert name(s) and contact information for the Principal Investigator}.

If you have questions about your rights or welfare as a participant, please contact the Oregon State University Institutional Review Board (IRB) Office, at (541) 737-8008 or by email at IRB@oregonstate.edu

1. **ASSENT STATEMENT**

Use if children will be enrolled in the study, unless there is no expectation that the children will be able to understand the information due to age or condition. If the study will not be explained to the children in the presence of the parent or guardian, please modify this language.

This research study has been explained to my child in my presence in language my child can understand. He/she has been encouraged to ask questions about the study now and at any time in the future.

1. **WHAT DOES MY SIGNATURE ON THIS CONSENT FORM MEAN?**

The IRB strongly discourages use of the "first person" statement in consent documents (using, "I have been fully informed about..."). Such statements ask subjects to make statements that the subject is not in a position to verify (e.g., the subject has no way to verify that the investigator has provided full and complete information).

Your signature indicates that this study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

**Do not sign after the expiration date:** The IRB will insert the appropriate date when the consent form is approved.

Participant's Name (printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

 (Signature of Participant) (Date)

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(Signature of Person Obtaining Consent) (Date)

Include any other applicable signature lines. Delete signature lines that are not applicable.

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(Witness or Translator) (Date)

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(Parent/Guardian/ Legally Authorized Representative) (Date)