The purpose of this template is to assist investigators and research personnel in drafting a research protocol and to facilitate consistency across 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.

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

**Notes on Submissions**

* Faculty are encouraged to make an appointment to discuss their projects and related documents with the IRB staff prior to formally submitting their initial applications. Drop-in advising hours for student researchers are posted on the IRB website.
* Anyone with access to individually identifiable information or who is interacting with the research subjects must be listed as a study team member. This includes, but is not limited to, staff who will recruit participants, obtain informed consent, administer surveys or questionnaires, or perform data analysis.
* All research staff are required to receive training in the ethical use of human participants in research. Please see the IRB website for education requirements.
* Proof read all documents prior to submission.

**Common Problems with Initial Submissions**

* Application submitted without having received substantive review by the PI.
* Application or other materials submitted by someone other than the PI.
* Discrepancies found between submitted documents (e.g. Application indicates total planned enrollment is 500, but the protocol indicates that enrollment numbers will range from 300 to 600.
* Incomplete compliance training for one or more study team members.
* Consent forms are not written in language appropriate to the target population.
* Study inappropriately targets students or faculty. See guidance on IRB website.
* Missing documents, such as letters of support, a copy of the grant or contract, test instruments (e.g. surveys, interview guides, questionnaires, etc.), or recruitment materials.

**RESEARCH PROTOCOL**

*Insert version date*

1. Protocol Title

**PERSONNEL**

1. Principal Investigator
2. Student Researcher(s)
3. Co-investigator(s)
4. Study Staff
5. Investigator Qualifications

Briefly describe qualifications of each study team member to fulfill their assigned roles on the project (e.g. study coordinator drawing blood is a certified phlebotomist; PI has a PhD in Psychology and is qualified to assess emotional distress in subjects; field interviewers have been trained by PI to obtain informed consent).

**Additional Instructions for Studies Involving Exercise Testing**

A study team member must be trained in exercise testing administration. Exercise test supervision requires the ability to deliver a level of emergency care, as well as experience in exercise testing interpretation and emergency plan practice.

The study team’s qualifications should align with the risk level for the population being studied. Please see the sample ***VO2max and Submax Testing Risk Stratification*** form and the ***Skills Required to Competently Supervise Exercise Tests*** sample worksheet for recommended documentation of these skills.

1. Training and Oversight

The PI is responsible for the conduct of the study, all human subject protections issues, and for the timely and complete submissions of IRB related documents. If OSU student or faculty researchers, external collaborators, and/or third parties (i.e., translators, survey administrators, or community members) are involved in any aspect of the study, please provide a detailed description of the training and oversight plan and explain how the PI will ensure protocol adherence. This plan should address training on issues such as consent and confidentiality, as well as tracking data collection to prevent over enrollment. In addition, please identify how oversight will be handled during any extended PI absences (sabbaticals, non-contract months, etc.).

**Additional Instructions for Studies Involving Exercise Testing**

The PI is responsible for ensuring the study team possesses the necessary skills related to exercise test supervision and the study population. The competencies for all study team members present during exercise should be documented.

1. Conflict of Interest

**Federal Guidelines require assurances that there are no conflicts of interest in research projects that could affect the welfare of human subjects. If this study presents a potential conflict of interest, additional information will need to be provided to the IRB.**

**Examples of potential conflicts of interest in research involving human subjects may include, but are not limited to:**

* A researcher or family member participates in research on a technology, process or product owned by a business in which the faculty member holds a financial interest.
* A researcher participates in research on a technology, process or product developed by that researcher.
* A researcher or family member has a financial or other business interest in an entity that is supplying funding, materials, products, equipment, research subjects, or the site of data collection for the current research project.
* A researcher or family member serves on the Board of Directors of a business that is supplying funding, materials, products, equipment, research subjects, or the site of data collection for the current research project.
* A researcher receives consulting income from an entity that is funding the current research project.

**Indicate whether any members of the study team, or any of their family members, have a financial or other business interest in the source(s) of funding, materials, or equipment related to this research study. If yes, please describe.**

**FUNDING**

1. Sources of Support for this project (unfunded, pending, or awarded)

**If unfunded, please indicate.**

**If funded, submit a copy of the grant, contract, or application. If the grant, contract, or application was submitted through Cayuse, a copy is not needed.**

Discrepancies between the description of research in the grant/contract and protocol must be explained in the protocol. Funds may not be expended for aspects of the research that involve human subjects until IRB approval has been obtained.

* Indicate internal and/or external funding source: This includes all sources of funding (e.g., Foundation, URISC, gift, departmental, private, or public sources).
* Grant/contract number:
* Cayuse number: N/A if funding is internal
* Name of PI on Grant:
* Grant title:
* Any external source(s) of material, equipment, drugs, supplements, or devices:

**DESCRIPTION OF RESEARCH**

1. Description of Research

A description of the significance and objectives of this project. Include the intended use for this research (e.g., thesis, publication, presentation, program evaluation, etc.). Include the aims and hypotheses to be tested, if any.

1. Background Justification

A brief description that should support the objectives of the research as well as enhancements in physical/mental health or knowledge that are anticipated from the research results. Discuss the need for the study and what gap in knowledge the study is expected to fill. Summarize relevant existing data, literature, past and ongoing studies, and how your study/project ties in with these.

1. Multi-center Study

Complete this section if OSU is not the only institution conducting this study. Example: OSU is conducting this study in collaboration with investigators at PSU and OHSU. **Required** information includes:

1. Name and Federal Wide Assurance (FWA) number of each participating institution:
2. Contact name and information for IRB of record at each participating institution:
3. Contact name and information for the Investigator(s) at each participating institution:
4. Role of each participating institution (e.g., recruitment, sample/data collection, sample/data analysis, etc.):
5. Method for assuring all participating facilities have the most current version of the protocol:
6. Method for confirming that all amendments and modifications in the protocol have been communicated to participating sites:
7. Method for communicating to participating facilities any serious adverse events and unanticipated problems involving risks to subjects or others:
8. Method of communicating regularly with participating sites about study events:
9. Approval letters from all of the IRBs of record for all participating sites (or indicate that they are pending and provide upon receipt):
10. Confirm that the PI at OSU will maintain documentation of all correspondence between participating sites and their IRBs of record:
11. External Research or Recruitment Site(s)

Complete this section if recruitment or other study activities will occur off campus (including online using websites external to OSU). **Required** information includes:

1. Name or description of each research site:
2. Name and role of appropriate authority from each site providing a letter of support or permission (when applicable):
3. Name of each recruitment site:
4. If recruitment method involves more than an advertisement (newspaper classified, flier, listserv email), name and role of appropriate authority from each site providing a letter of support:
5. Attach or include the final content of the ad or correspondence to be used for recruitment

Letters of support are generally required for studies that involve vulnerable populations (children, prisoners, pregnant women, or mentally or physically disabled persons). However, the IRB may request letters of support or permission from these external sites under additional circumstances to ensure appropriate protections and/or study feasibility . If Tribal Populations are enrolled, please provide the Tribal Council Resolution.

1. Subject Population

Below are items commonly described in this section:

* A description of participant characteristics: Indicate if the participant population is restricted to any gender or ethnic group;a justification is required if the participant population is restricted to a unique population [e.g., specific age range, gender, ethnic group, OSU students or employees (See the guidance on recruiting OSU students or employees: http://oregonstate.edu/research/irb/recruitment-students-and-employees-research-subjects)].
* Total target enrollment number: This is the total number of people that will sign a consent form or agree to participate in the research. This should not be a range and it should match the number on the application form. **NOTE: “Enrolled” means that these subjects have consented to participation in the study. These subjects count towards your total enrollment number even if they screen fail, withdraw, or are dropped from the study. The PI may submit a project revision form to increase the total enrollment number after IRB approval is obtained. If total enrollment is exceeded prior to IRB approval, the data on those subjects cannot be represented as having been gathered with IRB approval. This creates a problem for the use of that data in publications, dissertations, theses, and the like. If there is a screening process, it is suggested that the enrollment number be increased to account for screen fails. This should be explained in this section. Note: This section is only relevant to non-exempt research.**
* Description of any vulnerable population(s): Vulnerable populations include children, pregnant women, prisoners, non-English speakers, non-literate participants, adults lacking capacity to consent). Note: If your study is limited to adults, all enrolled subjects must have attained the legal age for consent to research under the applicable law of the jurisdiction in which the research will be conducted. Not all states consider 18 years to be the age of majority. Consequently, if the minimum age for subjects in the proposed study is 18 years and the study is open to individuals in multiple states, some participants may be considered children by their state law and will therefore be considered children for the purposes of IRB review. If the study is excluding pregnant women, any gender, racial, ethnic, or age group, provide justification.
* Inclusion and exclusion criteria: Provide a comprehensive list of criteria for enrollment.

**Additional Instructions for Studies Involving Exercise Testing**

Indicate the target population and risk level. Risk stratification should be completed utilizing the ACSM guidelines and/or the ***VO2max and Submax Testing Risk Stratification Worksheet***.

Please note: Women of childbearing age who are not medically sterile should be screened via urine pregnancy test and, if pregnant, should be excluded from VO2max testing.

* Recruitment: A detailed outline of the chronological sequence of how potential participants will be identified and recruited, and how privacy will be protected throughout this process. This should include a description of how the contact information for potential participants was obtained.

Prior to posting and/or distribution, the IRB must approve the final content of any and all advertisements and recruitment materials for studies that are conducted under the purview of the IRB. This includes but is not limited to recruitment via flyers, telephone, in-person, SONA, email, social media, and internet. **The final content of these recruitment materials should be submitted to the IRB with the initial application or project revision prior to their use.**

The IRB reviews the material to assure that it is accurate, not coercive or unduly optimistic, and not creating undue influence on the subject to participate, this includes, but is not limited to:

1. Statements implying a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and protocol
2. Claims, either explicit or implicit, that the activity, intervention, drug, biologic or device is safe or effective for the purposes under investigation
3. Claims, either explicit or implicit, that the activity, intervention, or test article is known to be equivalent or superior to any other drug, biologic or device
4. Use of terms like “new test,” “new treatment,” “new method,” or “new drug” without explaining that it is investigational
5. Promise of “free tests,” or “free treatment” when, in actuality, the participants will just not be charged for taking part in the investigation
6. Emphasis on compensation (e.g., bold type, larger font, etc.)
7. Inclusion of exculpatory language

Recruitment materials should be limited to the information the prospective subjects need to determine their eligibility and interest. Recruitment material and compensation plan cannot include a coupon or discount on the purchase price of the study product, if marketed.

Recruitment materials must include:

1. Title of the study
2. Name of the PI
3. Clear statement that this is research
4. Contact information for interested individuals

When appropriately worded, the following items may be included:

1. Condition being studied and/or the purpose of the research
2. Primary criteria that will be used to determine eligibility for the study
3. Time or other commitment required of the subjects
4. Location of the research
5. Potential direct or societal benefits
6. Description of compensation (note: do not emphasize with formatting)

Once approved by the IRB, recruitment material cannot be altered or manipulated in any way without prior IRB approval.

1. Consent Process
* **Written consent.** Standard written informed consent forms provide investigators with documentation that subjects gave informed consent. The IRB recommends that written documentation of informed consent be obtained whenever it is appropriate and possible to do so. However, the IRB may waive or alter the requirements for documentation of informed consent if obtaining written consent is inappropriate or introduces risk to the subjects. If, in the judgement of the principal investigator, a waiver is appropriate, explain why, and explain what method will be used to document consent. Examples of alternative documentation may include having a witness document in field notes that the subject was fully informed and gave consent; a note in the investigator’s records stating that the approved consent procedure was followed and informed consent was obtained.

If you are seeking a **waiver of documentation (signature) of informed consent**, please justify that request here and see the IRB website for the instructional template on “oral or alternative consent”. If you are proposing a consent procedure which does not include, or which alters some or all of the elements of informed consent, please indicate that you are seeking a **waiver of consent,** justify that request, and explain why the research could not practicably be carried out without the waiver. A list of the required elements of consent can be found here: <http://www.hhs.gov/ohrp/policy/consentckls.html>.

* **Describe where and when consent will be obtained.** The IRB is primarily concerned that consent be obtained prior to involving subjects in any study activities and that the location of the consent conversation protects subjects’ privacy when appropriate.
* **Obtaining consent online.**  If the consent process will take place in a web-based environment such as a chat room or via an online survey, please explain the mechanism provided for subjects to directly and privately communicate questions or concerns to a study team member. For example, a dedicated email address or virtual “room.”
* **Assessment of comprehension.** Explain how comprehension of consent information will be assessed and what questions will be asked of the subjects to determine comprehension of the study information. Open-ended questions are a useful tool for assessing comprehension. Examples include:
	+ What questions can I answer for you?
	+ So that I am sure that you understand what the study involves, would you please tell me what you think we are asking you to do?
	+ In your own words, can you tell me what the biggest risk to you might be if you enroll in this study?
* **Children**. Provide a plan for obtaining consent from parents or legal guardians. If obtaining parental consent is not a reasonable requirement to protect children in research, describe the alternative mechanism for safeguarding the rights and welfare of these subjects and indicate that you are requesting a waiver of parental permission. **Non-English speakers.** If non-English speaking subjects will be enrolled, describe the investigators language proficiency in the participants’ native language (conversational, fluent, do not speak the language). Indicate whether you will use a translator and/or an interpreter and explain their qualifications. Consider issues of confidentiality related to using a translator or interpreter and describe instructions that they will receive with respect to any sensitive information. Provide copies of all documents that participants will see translated into the language they speak and understand. If the translator is not a native speaker of the language, is not a professional translator, or does not have a master’s degree in languages, provide back translations of the documents into English.
* **Student Records.** If the study involves the collection of student records, beyond directory information, or directly recruits students from classrooms, please include the following information in the consent form:
	+ Data to be released (e.g. course grade, assignments, GPA, etc.)
	+ To whom it will be released (le.g. researchers, funding agency, publication outcomes, etc)
	+ For what purpose the data is being released
	+ A field for the participant to include the date consent was given

Additionally, written consent must be obtained from the participants. This includes electronic consent if it is obtained within an authenticated environment (e.g. Blackboard, Canvas, ONID.)

* **Signatures on a consent form.**

Note: Not applicable if you are requesting a waiver of signature and/or are using a verbal consent process.

* + Subject (required): Subject signatures indicate that the study has been explained to them, all of their questions have been answered, and they agree to be in the study.
	+ Researcher (required): Researcher signatures indicate that the study was explained to the subject, comprehension was assessed and found to be sufficient, and the subject provided consent to participate in the study.
	+ Witness signature: A witness must be an impartial adult who is not a member of the study team, or a family member of the subject. Their signature on the consent form indicates that they observed the consent process, the study was explained to the subject, all of the subject’s questions have been answered, and that consent is being given voluntarily. A witness signature is required when:
		- using a foreign language short form process, or
		- when obtaining consent from a participant who has the capacity to consent but is unable to read, write, talk, or is blind. In this case the individual providing consent must be able to indicate consent in some way and that must be indicated on the consent form (e.g., mark on the signature line, spoken, raised arm, nodded, etc.).
	+ Translator: If a translator is utilized during the consent process, their signature may be required. A translator’s signature indicates that they translated the consent process, including any questions asked by the subject, that all of the subject’s questions have been answered, and that consent is being given voluntarily.
	+ Parent, guardian, or legally authorized representative: These signatures may be required when the subject is a minor or in the event that the subject has diminished capacity to provide consent.
* **Significant new findings:**  Significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation must be provided to the subject. For example, a change in the terms of service or license agreement with an online survey tool which results broader sharing of user data, may impact a subject’s willingness to provide data via that website. Similarly, a discovery that the study intervention had negative affects that were unforseen at the beginning of the study, could impact a subject’s willingness to continue with the study activities. When appropriate for the study, a statement regarding the disclosure of significant new findings should be included in the consent process. See the *Informed Consent Template* for sample language.
* **Adult subjects with diminished capacity to consent.**
* Describe how capacity for consent will be determined if some or all subjects lack capacity to consent.
* If subject’s capacity to consent may decline during the study, explain the plan for ongoing assessment of the subject’s ability to understand that they are participating in a study. Examples may include subjects with beginning stages of dementia.
* If a subject may regain capacity to consent after being enrolled in the study through a surrogate consent process, describe the plan for assessing capacity to consent and the consent process.
* Describe the procedure for identifying a surrogate decision maker for a subject unable to consent for him/herself.
1. Assent Process

Things to consider when describing the assent process:

* This section should demonstrate an understanding of the nature of assent and how to judge to whether or not an individual is capable of participating in the process.
* Indicate who will discuss the study with the child and describe their training in presenting research in a clear and age-appropriate fashion. Outline what information will be discussed. The IRB will want to see a guide or outline of the language the investigator will use in this discussion. The wording should capture the essential elements in age-appropriate language.
* Indicate whether an oral assent process is to be used (typically for ages 0-7) or if an assent document will be used (typically for children ages 8 – 17).
* If children enrolled in this study will reach the age of majority (18) before their study participation ends, describe the plan and process for obtaining their consent to continue.
* Parental consent may only be waived in rare cases. Parental consent and parental notification are not the same. However, in cases where consent is waived, notification may be appropriate. If you want the IRB to waive the assent requirement, indicate the appropriate justification:
* The ages, maturity, or psychological state of the children to be enrolled make them incapable of providing assent; or
* The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research; or
* The research involves no more than minimal risk to children, and the research could not practicably be carried out without the waiver or assent.
1. Eligibility Screening

While investigators are encouraged to describe a study and any eligibility requirements to interested individuals prior to obtaining informed consent to participation, collection of information from those individuals for the purposes of pre-screening must generally occur after informed consent has been obtained.

If the study involves a screening process, explain whether the eligibility screening will take place before or after informed consent has been obtained. If after, indicate what data will be collected; and what will be done with the data if the person screen fails. If before, a waiver of documentation of signed informed consent to collect screening information may be requested. Add a description of the information that will be provided to the potential participant before screening questions are asked. Provide a screening or eligibility checklist that will be used with each participant.

**Additional Instructions for Studies Involving Exercise Testing**

Screening must contain a health history including cardiovascular medical history, risk factors, symptoms, and other health issues. Please refer to the sample ***Health History Questionnaire***.

It is suggested that you utilize an eligibility screening form and submit it to the IRB for review. Please also refer to the ***VO2max and Submax Testing Risk Stratification Worksheet*** to determine risk level. Please provide rationale if deviating from these recommendations and provide substitute screening and risk evaluation procedures.

1. Methods and Procedures
* This section should include:
	+ a full description of the methods and procedures to be followed during this research project
	+ a step-by-step explanation of each procedure that will be followed
	+ identification of any experimental activities/evaluation activities
	+ the estimated time commitment for a participant’s involvement
* procedures for analysis and interpretation of dataIf participants will be audio or video recorded, indicate whether it is required in order to participate.
* If your study is designed to be implemented in phases, where one phase is dependent upon the outcome of another, please describe your plan for obtaining IRB approval for each phase prior to initiating subsequent phases.
* If your study involves the use of surveys, interviews, focus groups, or questionnaires, the final content of these items should be submitted to the IRB either within this section of the protocol or as an attachment.
1. If your study involves a workshop or a class as the research intervention, provide a copy of the curriculum. Compensation

Include a description of any compensation that will be given to participants. Include details concerning the conditions under which research participants would receive partial payment or no payment at all (e.g., withdrawing early from the study).

When the study involves multiple activities or multiple visits, the entire payment should not be contingent upon completion of the entire study. Completion bonuses, if offered, should not be so great that it unduly influences participants to remain in the study if they wish to withdraw.

Raffles and Lotteries may be permitted under certain circumstances. Please see the IRB website for more information. Please note: compensation cannot include:

1. coupons or discounts on the purchase price of the study product, if marketed
2. Costs

Describe any costs to participants that are associated with the study (e.g. parking, travel, etc.). This section should not include costs incurred by the study team or the study.

1. Drugs or Biologics
* List all drugs or biologics to be used in this study. Include the following for each drug or biologic:
	1. Name:
	2. Chemical formula:
	3. Dosage strength(s):
	4. Method/route of administration :
	5. Mechanism of action:
	6. Known drug interactions:
	7. Manufacturer/Sponsor:
	8. Name of supplier:
	9. IND number if applicable and letter from the FDA or industry sponsor setting forth the IND number:
	10. Documentation of approval for use in humans:
	11. Documentation or certification of quality or purity:
* **If there is no IND, provide documentation establishing that the clinical investigation of the investigational drug at issue falls within one of the following categories:**
1. The drug being used in the research is lawfully marketed in the United States and all of the following requirements are met:
	* The research is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug
	* The research is not intended to support a significant change in the advertising for the product;
	* The research does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product
	* The research is conducted in compliance with the requirements for IRB review and informed consent [21 CFR parts 56 and 50, respectively]
	* The research is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 CFR 312.7]
	* The research does not intend to invoke FDA regulations for planned emergency research [21 CFR 50.24].
2. The research only involves one or more of the following: (a) Blood grouping serum, (b) Reagent red blood cells or (c) Anti-human globulin;
3. For clinical investigations involving an in vitro diagnostic biological product, an IND is not necessary if a) it is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure; and b) it is shipped in compliance with 312.160
* Rationale for choosing the drug or substance dose or for choosing the device to be used:
* Summary of preclinical and early human studies (for studies with an IND):
* Justification and safety information if FDA approved drugs will be administered for non-FDA approved indications or if doses or routes of administration or subject populations are changed:
* Justification and safety information if non-FDA approved drugs without an IND# will be administered:
* Plan for the storage, dispensing, handling, inventory control, and disposal of investigational and FDA-approved drugs and biologics:
* Explain whether the use of the test article involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with its use:

**Note**: If there is any ambiguity about whether an IND is needed, the IRB may request that the PI provide a determination from the FDA. The PI may choose to request such a determination pre-emptively by taking the following steps:

* Complete FDA forms 1571 and 1572. These forms are available on the FDA website: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm071073.htm>
* Submit completed forms to FDA, along with a copy of the protocol to be submitted to the IRB.
* Include cover letter specifically requesting a written determination regarding the need for an IND.
* FDA will respond within 30 days. The response may then be submitted to the IRB.
1. Dietary Supplements or Food

A dietary supplement is a product taken by mouth that is intended to supplement the diet and that contains one or more "dietary ingredients." The "dietary ingredients" in these products may include

* vitamins
* minerals
* herbs or other botanicals
* amino acids
* other substances found in the human diet, such as enzymes

If you intend to make claims about disease prevention or treatment, you need an IND. **Contact the FDA before submitting application materials to the IRB.** If you are planning to limit claims to structure and function, you may not need an IND.

* List all dietary supplements or foods to be used in this study. If foods are used that are purchased in a grocery store or are on the FDA GRAS list (<http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=scogsListing>), please state, and indicate where preparation, handling, and storage will occur. Otherwise, include the following for each supplement or food:
	1. Name:
	2. Chemical formula:
	3. Dosage strength(s):
	4. Method/route of administration:
	5. Mechanism of action:
	6. Known drug interactions:
	7. Manufacturer/Sponsor:
	8. Name of supplier:
	9. IND number if applicable and letter from the FDA or industry sponsor setting forth the IND number:
	10. Documentation of approval for use in humans:
	11. Documentation or certification of quality or purity:
* **If there is no IND, confirm that you will be limiting claims to structure and function or provide documentation establishing that the clinical investigation of the supplement at issue falls within one of the following categories:**
1. The supplement being used in the research is lawfully marketed in the United States and all of the following requirements are met:
	* The research is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug
	* The research is not intended to support a significant change in the advertising for the product;
	* The research does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product
	* The research is conducted in compliance with the requirements for IRB review and informed consent [21 CFR parts 56 and 50, respectively]
	* The research is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 CFR 312.7]
	* The research does not intend to invoke FDA regulations for planned emergency research [21 CFR 50.24].
2. The research only involves one or more of the following: (a) Blood grouping serum, (b) Reagent red blood cells or (c) Anti-human globulin;
3. For clinical investigations involving an in vitro diagnostic biological product, an IND is not necessary if a) it is intended to be used in a diagnostic procedure that confirms the diagnosis made by another, medically established, diagnostic product or procedure; and b) it is shipped in compliance with 312.160
* Rationale for choosing the supplement and dose or food product:
* Summary of preclinical and early human studies (for studies with an IND):
* Justification and safety information if over-the-counter supplements will be administered for non-approved indications or if doses or routes of administration or subject populations are changed:
* Explain whether the use of the supplement involves a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with its use:
* Provide a plan for the storage, dispensing, handling, inventory control, and disposal of supplements:

**Note**: If there is any ambiguity about whether an IND is needed, the IRB may request that the PI provide a determination from the FDA. The PI may choose to request such a determination pre-emptively by taking the following steps:

* Complete FDA forms 1571 and 1572. These forms are available on the FDA website: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm071073.htm>
* Submit completed forms to FDA, along with a copy of the protocol to be submitted to the IRB.
* Include cover letter specifically requesting a written determination regarding the need for an IND.
* FDA will respond within 30 days. The response may then be submitted to the IRB.
1. Medical Devices

A medical device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

* recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,
* intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
* intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of it's primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its primary intended purposes.

For additional assistance in determining whether or not the device you plan to use is a “medical device”, see: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/ucm051512.htm>

http://oregonstate.edu/research/irb/sites/default/files/is\_it\_a\_medical\_devices.pdf

**Significant Risk vs. Non-Significant Risk**

**Significant risk devices** present a potential for serious risk to the health, safety, or welfare of a subject. Significant risk devices may include implants, devices that support or sustain human life, and devices that are substantially important in diagnosing, curing, mitigating or treating disease or in preventing impairment to human health. Examples include sutures, cardiac pacemakers, hydrocephalus shunts, and orthopedic implants.

You must obtain FDA approval prior to proceeding with your application to the IRB. Please review the FDA website for instructions on when and how to submit an Investigational Device Exemption Application.

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/ucm046164.htm>

<http://oregonstate.edu/research/irb/sites/default/files/medical_devices-exempt.pdf>

http://oregonstate.edu/research/irb/sites/default/files/medical\_devices-sigrisk.pdf

**Non-significant risk** devices are devices that do not pose a significant risk to the human subjects. Examples include most daily-wear contact lenses and lens solutions, ultrasonic dental scalers, and foley catheters. FDA approval is not required for these devices.

**If you plan to use a device and no IDE is required, provide documentation establishing that the investigation of the device falls within one of the following categories:**

1. A clinical investigation of a FDA-approved, legally marketed device that is being used in accordance with its labeling.
2. A clinical investigation of a device that the FDA has determined to be substantially equivalent to a device in commercial distribution immediately before May 8, 1976 and that is used or investigated in accordance with the labeling FDA reviewed under Subpart E of 21 CFR Part 807 in determining substantial equivalence;
3. Clinical investigation of a Non-Significant Risk Device.
4. A clinical investigation involving a Diagnostic Medical Device if it complies with FDA labeling requirements and if the testing: (a) is noninvasive; (b) does not require an invasive sampling procedure that presents significant risk; (c) does not by design or intention introduce energy into a subject; and (d) is not used as a diagnostic procedure without confirmation by another medically established diagnostic product or procedure.
5. Consumer preference testing, testing of a modification or testing of a combination of devices if the devices(s) are legally marketed devices and if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.
6. Clinical investigation of a device intended solely for veterinary use.
7. Clinical investigation of a device solely intended for Research with laboratory animals that contains the labeling “Caution – Device for investigational use in laboratory animals or other tests that do not involve human subjects.”
* Rationale for choosing the device to be used:
1. Radiation
* Complete Radiation Safety Form
* Include risk of exposure in consent form
1. Biological Samples
* Complete Biological Materials Form
* Indicate whether samples from living individuals will be studied and whether the samples will be obtained prospectively or whether the samples are pre-existing (“on the shelf” prior to the submission of this application).
* If blood samples will be collected, provide the maximum amount to be collected in an 8 week period and the frequency of collection.
* Indicate whether identifiers or codes be retained that could link the identity of the subject to the sample and describe procedures to protect against unauthorized use and loss of confidentiality of the samples or inadvertent release of confidential information.
* If the study involves accessing medical records, explain how permission for this access will be obtained.
* If any laboratory testing is being conducted, describe the purpose of the tests and whether results will be disclosed to subjects and/or their treating physician.

***Please note: Results from lab tests, including urine pregnancy tests, cannot be disclosed to subjects unless the lab conducting the test is CLIA-certified.***

* Indicate whether specimens will be collected for "banking" and future research and describe procedures for obtaining consent for future studies of existing 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. The information in the consent form should convey the disease, condition, or specific field of study for future projects.
* For DNA banking studies, address the following questions:
* Will DNA be stored or shared? If shared, will the subject's identity be known by any new recipient investigators?
* Will the subject be contacted in the future by the investigator to obtain updated clinical information?
* How can the subject opt out of any distribution or subsequent use of his/her genetic material?
* If the study involves genetic testing, address the following questions:
	+ Will test results be disclosed to the subject or their physician?
	+ Will disease risk be quantified, including the limits on certainty of the testing?
	+ Will a change in a family relationship be disclosed, such as mistaken paternity?
	+ Does the subject or family member have the option not to know the results? How will this decision be recorded?
	+ Could other clinically relevant information be uncovered by the study? How will disclosure of this added information occur?
	+ Do any practical limitations exist on the subject's right to withdraw from the research, withdraw data, and/or withdraw DNA?
	+ Is the subject permitted to participate in the study if they decline to participate in the genetic testing?
1. Anonymity or Confidentiality
* Whether or not names are being collected from subjects, the subjects should not be described as “anonymous” if their identities are known to investigators (i.e., interviews take place in person, email addresses are used, etc.). Describe the steps that will be taken to minimize the chances of a breach of confidentiality. This information should correspond to the information that appears in the same section of the consent document. If there is a risk of harm associated with a potential breach of confidentiality, please articulate that risk in the section below.
* Describe plan for secure storage and retention of data and/or samples. This plan must be in line with the IRB Data Security Guidance (http://oregonstate.edu/research/irb/data-security)
* Indicate where, confirm that data will be stored for a minimum of seven years post study termination, and in what format (paper, digital or electronic media, video, audio, or photographic) data will be kept
* Describe what security provisions will be taken to protect this data (password protection, encryption, etc.)
* Indicate whether you will record any direct identifiers (names, social security numbers, addresses, telephone numbers) and explain why it is necessary to record findings using these identifiers
* When applicable to protect confidentiality, describe the coding system you will use to protect against disclosure of these identifiers
* Indicate whether you will retain a link between study code numbers and direct identifiers after the data collection is complete and, if yes, explain why this is necessary and state how long you will keep this link
* Indicate whether you will provide the link or identifiers to anyone outside the research team and, if yes, why and to whom
* Indicate whether you will provide coded or de-identified data and/or samples to anyone outside of the research team and, if yes, why, to whom, and for what purpose
* If recruiting from the Center for Healthy Aging Research (CHAR) Life Registry, indicate that you will provide CHAR with a list of participants.
* Indicate how the data will be reported in publications (e.g. in aggregate form, using direct quotes) This information should indicate whether participants may be identifiable, directly or indirectly, including whether the name of their affiliated organization will be identified, if applicable
* Will you place a copy of the consent form or other research study information in the subjects’ record such as medical, personal or educational record? If yes, explain why this is necessary and confirm that this information is disclosed in the consent form.
* While any person may make a report if they have reasonable cause to believe that a child was abused or neglected, Oregon law mandates that certain persons who suspect child abuse or neglect report this to the appropriate authorities. **Under Oregon law, all OSU employees are considered to be mandatory reporters.**

In situations where conditions of abuse or neglect might be revealed, mandated reporters should make themselves known as such to parents of children under age 18, to subjects who are children, and to subjects who are potential victims of abuse or neglect. If the nature of the study or target population lends itself to the possibility that mandatory reporting may be required of the study team, explain how such circumstances will be handled.

* If the study involves sensitive information and a Certificate of Confidentiality from the NIH will be sought for this study, please indicate that here and in the consent document. For more information on Certificates see: http://grants.nih.gov/grants/policy/coc/
1. Risks
* This section should include a description of any potential physical, mental/emotional, legal, financial, insurance, employment, or social risks. It is not sufficient to describe the risks as “minimal” without identifying what those risks are.
* In all cases where subjects are known to the investigators, there is the chance of a breach of confidentiality. However, if there is no potential for harm associated with such a breach, it need not be listed in this section. The ways in which the potential for a breach of confidentiality will be minimized should be articulated in the anonymity and confidentiality section above.
* Investigators should consider risks to entire groups under study (e.g. tribes, ethnic or racial groups, economic classes).
* Risks involved in web-based research almost always include the possibility of a breach of confidentiality. Risks associated with internet research may also include:
	+ a subject’s loss of access to a site if participation in research via the site is in violation of the company’s Terms of Service
	+ the existence of data on backups or server logs beyond the timeframe of the research project
	+ interception, corruption, loss, or destruction of data.
	+ data may arrive late, be incomplete, or contain viruses
* If deception is to be used, please include a detailed justification and a description of any debriefing process. Deception occurs as the result of investigators providing false or incomplete information to participants for the purpose of misleading research subjects. For additional requirements, please review the IRB policy on deception in research (http://oregonstate.edu/research/irb/sites/default/files/irbpoliciesandprocedures.pdf).
* Describe all steps taken to minimize risks. When appropriate, you may refer to the above section on anonymity and confidentiality.
* If the study involves risk, explain the plan for reporting adverse events or unanticipated problems (e.g. breach of confidentiality, incarcerated participant, or an unresolved complaint).
* **Risks of VO2max Testing:**
* Acute exercise may present a risk of untoward events, including 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
* 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
* **Additional Instructions for Studies Involving Exercise Testing**

This section must include:

* + **Monitoring procedures**
		1. To include type of monitoring to be performed during test and by whom
	+ **Individual stopping rules**
		1. If you choose to utilize different criteria than the ASCM stopping rules recommended below, please provide rationale for deviating from these recommendations and provide alternate stopping rules.
		2. *Provided as a guide, the ACSM recommends the following* ***stopping rules****:*
			1. *Subject requests to stop*
			2. *Onset of angina or angina-like symptoms*
			3. *Drop in SBP of >10mmHg*
			4. *Excessive rise in BP*
			5. *Shortness of breath, wheezing, leg cramps or claudication*
			6. *Signs of poor perfusion: light-headedness, confusion, ataxia, pallor, cyanosis, nausea or cold/clammy skin*
			7. *Failure of heart rate to increase with increased exercise intensity*
			8. *Noticeable change in heart rhythm*
			9. *Physical or verbal manifestations of severe fatigue*
			10. *Failure of the testing equipment*
	+ **Emergency procedures**
		1. Minimum requirements include:
			- AED located in same room as testing equipment
			- Routine testing of AED
			- Emergency action plan present at testing site
	+ **Equipment handling and disinfection procedures**
		1. In addition, provide a copy of the manufacturers’ guidelines for applicable equipment
1. Benefits

Describe benefits to the individual participants and society

1. Assessment of the risks and benefits

Provide an assessment of the risk related to the benefit. The potential benefits to subjects and the knowledge gained for society and science must outweigh the risks.