IRB Review Checklist	***IRB Campbell Univ. #____***		
I. Assessment of Protocol	**YES**	**NO**	**N/A**
➢ Is the proposed research scientifically sound? Comment:	☐	☐	☐
➢ Will the research design yield useful data?	☐	☐	☐
II. Assessment of Subject Population	**YES**	**NO**	**N/A**
➢ Is the enrollment of subjects equitable (e.g., subject population included/excluded, risks of coercion in recruitment)? Comment:	☐	☐	☐
➢ Are the subjects appropriate for research? Comment:	☐	☐	☐
➢ Does the study involve subjects from vulnerable populations? Comment:	☐	☐	☐
➢ If applicable, are appropriate safeguards in place for vulnerable populations? Comment:	☐	☐	☐
III. Assessment of Risk	**YES**	**NO**	**N/A**
➢ Is this research more than minimal risk? Comment:	☐	☐	☐
➢ Are subjects being subject to unnecessary risks? Comment:	☐	☐	☐
IV. Minimization of Risk	**YES**	**NO**	**N/A**
➢ Are adequate provisions in place to minimize research risks (i.e., frequent monitoring, qualified personnel, adequate research setting, response to emergency situations)? Comment:	☐	☐	☐
➢ Does monitoring include a data safety monitoring board? Comment:	☐	☐	☐
➢ Is an annual continuing review sufficient for this research? Comment:	☐	☐	☐
V. Assessment of Anticipated Benefits	**YES**	**NO**	**N/A**
➢ Is there direct benefit to the subjects? Comment: in terms of knowing if they are “physically fit”	☐	☐	☐

➢ Does the research provide therapeutic benefit? Comment:	☐	☐	☐
➢ Does the research primarily benefit society (i.e., involves procedures performed for research purposes only without direct benefit to the subjects)? Comment: see comments in I	☐	☐	☐
➢ Is compensation offered to the subjects? Comment:	☐	☐	☐
➢ Do the benefits of the research outweigh the risks? Comment:	☐	☐	☐
VI. Informed Consent	**YES**	**NO**	**N/A**
➢ Does the informed consent include the eight required elements (see page 4)? Comment:	☐	☐	☐
➢ Is the informed consent appropriately documented? Comment:	☐	☐	☐
➢ Is the consent form in a lay language? Comment:	☐	☐	☐
➢ Will potential subjects be approached in an appropriate manner? Comment:	☐	☐	☐
➢ Will qualified study personnel be administering consent to the subject? Comment:	☐	☐	☐
VII. Confidentiality	**YES**	**NO**	**N/A**
➢ Does the research involve collecting private health information (PHI)? Comment:	☐	☐	☐
➢ Is there adequate provision for monitoring the data collection to ensure the safety of subjects? Comment:	☐	☐	☐
➢ Are the provisions for protecting privacy adequate? Comment:	☐	☐	☐
➢ Are adequate provisions in place to protect confidentiality? Comment:	☐	☐	☐
➢ Will participation be included in the subjects' medical records? Comment:	☐	☐	☐

VIII. Other Considerations	YES	NO	N/A
➢ Does the research involve genetic testing? Comment:	☐	☐	☐
➢ Will samples be kept for future, unspecified use? Comment:	☐	☐	☐
➢ Is this FDA-regulated research? Comment: |	☐	☐	☐
➢ Is there any conflict of interest for the PI or other study personnel? Comment:	☐	☐	☐

Reviewer Name:

Signature:

Date:

If you have additional comments or questions / concerns on the proposed research, please attach as a separate sheet to this form.

Basic IRB Review Information

The following criteria are taken from OHRP's Institutional Review Board Guidebook, Chapter III (http://www.hhs.gov/ohrp/irb/irb_chapter3.htm).

The IRB must:

1. Identify the risks associated with the research, as distinguished from the risks of therapies the subjects would receive even if not participating in research.
2. Determine that the risks will be minimized to the extent possible.
3. Identify the probable benefits to be derived from the research.
4. Determine that the risks are reasonable in relation to be benefits to subjects, if any, and the importance of the knowledge to be gained.
5. Assure that potential subjects will be provided with an accurate and fair description of the risks or discomforts and the anticipated benefits.
6. Determine intervals of periodic review, and, where appropriate, determine that adequate provisions are in place for monitoring the data collected.
7. Determine the adequacy of the provisions to protect the **privacy** of subjects and to maintain the **confidentiality** of the data.
8. Determine that appropriate additional safeguards are in place to protect the rights and welfare of those subjects who are likely to be members of a vulnerable population (e.g., mentally disabled).

Definitions:

Benefit: A valued or desired outcome; an advantage.

Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45.CFR.46.102(i)]. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

Risk: The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk."

Required elements for an Informed Consent:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
2. A description of any reasonably foreseeable risks or discomforts to the subject.
3. A description of any benefits to the subject or to others which may reasonably be expected from the research.
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.