A. FUNCTION. The federal government requires the University of Idaho (University) to designate an Institutional Review Board (IRB) to ensure that human participant subject research conducted under the auspices of the University meets federal requirements. Under the approved federal-wide assurance (FWA00005639) for the University, the IRB shall apply the regulations set forth by United States Department of Health and Human Services (HHS) (www.hhs.gov) at 45 CFR 46 to all federally funded human participant subject research, regardless of funding source, and shall be guided by the ethical principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects. All non-federally funded or unfunded human participant subject research shall comply with these regulations unless otherwise specified by University policy. The IRB shall also apply the human participant subject research regulations established by the Food and Drug Administration for clinical investigations involving drugs, biologics, medical devices, and other test articles. (21 CFR 50; 56; 312, and 812). The IRB shall not approve FDA-regulated human participant subject research without prior approval for such research from the Office of Research and Economic Development. The IRB shall act in conformance with other federal laws and regulations germane to human participant subject research and with applicable state and local law that serves to elucidate and supplement federal regulations for human subject research. [See FSH 5200]

A-1. Human participant subject research that has been approved by the IRB may be subject to further review and approval or disapproval by University officials. However, a University officials may not approve such research, or that portion of a research project that constitutes human participant subject research, if that it has not been approved by the IRB. (45 CFR 46.112)

A-23. The committee also serves as an advisory body to the Vice President for Research and Economic Development for matters related to human subjects/participants research.

B. STRUCTURE AND MEMBERSHIP.

B-1. The IRB is composed of at least five (5) members appointed by the VP for Research and Economic Development. Members shall have varying backgrounds to promote complete and adequate review of research activities commonly conducted at the University. The IRB is chaired by a faculty member-chaired committee.

B-2. It shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted at the University of Idaho [45 CFR 46.107(a)].

B-23. The Director of Research Assurances position of Chief Research Compliance Officer serves in the capacity of as an ex officio non-voting standing committee member to assist in representing institutional commitments and regulations, [45 CFR 46.107(a)].

B-4. The IRB shall include at least one member whose primary concerns are in scientific areas and one member whose main primary concerns are in nonscientific areas [45 CFR 46.107(c)].

B-5. The IRB shall include one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution [45 CFR 46.107(d)].

B-6. At its discretion, the IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB [45 CFR 46.107(f)].
B-7. The Signatory Official, who is the Vice President for Research and Economic Development may remove and replace a committee member at any time if and when he/she determines that the member is unwilling or unable to carry out committee functions.

B-8. Alternates. The IRB Chair, or designee, may select an alternate member to substitute for, with vote, an absent voting member at a convened meeting. The alternate member shall have similar expertise as the absent voting member for whom they are serving as a replacement.

B-9. The Vice President for Research and Economic Development appoints all members of the IRB, including the alternates.