1 PURPOSE
1.1 The purpose of this SOP is to outline the membership of the Florida State University (FSU) Institutional Review Board (IRB).

2 REVISIONS FROM PREVIOUS VERSION
2.1 June 1, 2006, August 2, 2018

3 POLICY
3.1 This SOP originates from and is managed at the discretion of the Office of The Vice President for Research, and therefore is not subject to the requirements of “SOP: Standard Operating Procedures (HRP-071).”

4 RESPONSIBILITIES
4.1 The Vice President for Research (VPR) or designee oversees these procedures.

5 PROCEDURE
5.1 Each IRB is required to have a minimum of five members, with varying backgrounds to promote complete and adequate review of research commonly conducted by FSU.

5.2 The IRB membership must be sufficiently qualified by experience and expertise and the diversity of its members, including consideration of race, gender, and cultural backgrounds as well as sensitivity to issues such as community attitudes, to promote respect for the IRB’s advice and counsel regarding human subjects protection. The IRB must be able to ascertain the acceptability of proposed and continuing research based upon knowledge of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The composition and size of the IRB must be adequate in light of the anticipated scope of FSU’s research activities, the types of subject populations likely to be involved, and the size and complexity of FSU.

5.3 If the IRB regularly reviews research involving vulnerable subjects, the IRB shall include one or more members who have knowledge about and are experienced in working with these subjects. To fulfill this requirement, the IRB may alternatively invite nonvoting individuals to assist in the review of research.

5.4 Each IRB shall include at least one member whose primary interests are in a scientific area, one member whose primary interests are in a non-scientific area, and one member who is, other than IRB membership, not affiliated with FSU and who is not part of the immediate family of a person who is affiliated with FSU.

5.5 The IRB shall not have a member participating in initial, continuing or other review of any project in which the member has a conflicting interest, except to provide information requested by the IRB. If a member of the IRB has a conflict at a meeting, the nature of the conflict must be declared, and that member must be recused from the deliberation and voting portions of the meeting to ensure that the IRB’s discussion and decision are free from undue influence, in accordance with “SOP: Conflicting Interests of IRB Members (HRP-050).”

5.6 The IRB Chair is formally appointed to a two-year term at the discretion of the VPR or designee, votes as an active member of the IRB, and possesses the following qualifications:

5.6.1 The individual must have experience on an IRB.

5.6.2 The individual must have a good understanding of the Code of Federal Regulations as they apply to the protection of human subjects in research and the policies and procedures of the IRB.

5.6.3 The individual must have sufficient time at his/her disposal to perform the duties and responsibilities of the Chair.

5.7 IRB members are formally appointed to a two-year term by the VPR or designee, which is renewable by the VPR or designee. When the IRB, Office for Human Subjects Protection (OHSP) and/or the VPR determine that a new member is necessary, the OHSP Director will receive names of possible candidates for consideration from IRB members, campus Deans,
Associate Deans, or via direct request from interested parties. The VPR or designee shall review the qualifications of the candidate and make appointments accordingly.

5.8 IRB member alternates may only vote in place of a missing regularly appointed member. Each alternate member must have qualifications similar to the member he/she replaces. The VPR or designee formally appoints alternates for two-year terms, renewable by the VPR or designee. Alternate members will be notified and provided with all materials in advance of a meeting they will attend in place of the regular member, and will have full voting status at the time of the meeting. The minutes must document when an alternate member replaces the appointed member.

5.9 FSU must assure that the IRB is able to function in an independent and credible manner. Only members specifically authorized by the VPR or designee will be appointed to the IRB.

5.10 IRB members are expected to complete required training, to attend the majority (more than 50%) of meetings within each calendar year, and to promptly notify the OHSP or the IRB Chair of any absence. If an IRB member fails to meet the required attendance, that member may be removed from membership. No voting by proxy is permitted.

5.11 IRB members may receive a non-salary funding allocation for their service on the committee, as determined by the Office of Research, in accordance with “SOP: Funding Allocated to IRB Members (7-IRB-40).”

5.12 Only the VPR or designee, in consultation with the IRB Chair, is authorized to remove a member from the IRB.

5.13 Only the VPR or designee is authorized to remove an IRB Chair.

6 MATERIALS
6.1 SOP: Conflicting Interests of IRB Members (HRP-050)
6.2 SOP: Funding Allocated to IRB Members (7-IRB-40)

7 REFERENCES
7.1 45 CFR §46.107 and related DHHS Guidance
7.2 Florida State University System, Board of Governors Regulations:1.001(3)(m)
7.3 Florida State University Policy 7-IRB-0