

SOP: Membership of the FSU IRB			
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**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, October 8, 2019

**3 POLICY**

3.1 This SOP implements FSU Policy 7A-35 (Policy on ACUC and IRB Committee Member Appointment, Terms of Service, and Compensation), and describes related procedures.

**4 RESPONSIBILITIES**

4.1 The VPR or designee oversees these procedures.

**5 PROCEDURE**

5.1 The composition and size of the FSU 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. In every case, 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 FSU IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

5.3 If the IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects. To fulfill this requirement, the IRB may alternatively invite nonvoting individuals to assist in the review of research.

5.4 The 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, at the discretion of the VPR, to a renewable two-year term. Each chair should be rotated after two terms to allow the Vice Chair to assume the role of Chair.

5.6.1 The IRB Chair votes as an active member of the Board, and possess the following qualifications:

5.6.1.1 The individual must have experience on an IRB.

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- 5.6.1.2 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.
  - 5.6.1.3 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 an initial two-year term by the VPR, which is renewable by the VPR for another two-year term, for a maximum of two consecutive terms or four years total. Members may be appointed to a third term at the discretion of the VPR due to extenuating circumstances as determined by the VPR. When new members are necessary, the responsible director of the Office for Human Subjects Protection will work with the IRB Chair to identify and review possible candidates for consideration. The responsible director and IRB Chair will forward screened candidates to the VPR. The VPR shall review the qualifications of forwarded candidates and make final appointment decisions. The VPR will issue formal appointment letters to new members specifying terms of service.
  - 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 and to attend the majority (more than 50%) of meetings within each calendar year, and 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
  - 7.4 Florida State University Policy 7A-35