

IRB Standard Operating Procedure

SOP	Composition of the IRB	Effective Date
2	_	1/1/2023

PURPOSE

To define membership of the IRB committee—excluding Chair, Institutional Officials, and Legal Representatives.

DEFINITIONS

None

POLICY

The IRB shall adopt § 56.107 without modification. Hence,

- (a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, 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. In addition to possessing the professional competence necessary to review the specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. * * * The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with those subjects.
- (b) Every nondiscriminatory effort will be made to ensure that no IRB consists entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. No IRB may consist entirely of members of one profession.
- (c) Each IRB shall include at least one member whose primary concerns are in the scientific area and at least one member whose primary concerns are in nonscientific areas.

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- (d) Each IRB shall include at least 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.
- (e) No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.
- (f) An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of complex issues which require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

RESPONSIBILITIES

IRB Chair is charged with ensuring SOP 2.

REGULATIONS

§ 56.107

CONTACT INFORMATION

Please direct questions or concerns about this policy to:

Contact Title/Role

IO

Brett Gordon IRB Chair

DISCLAIMER

The University reserves the right to modify or amend sections of this IRB SOP at any time at its sole discretion. This IRB SOP remains in effect until such time as a suitable Institutional Official or IRB Member requests review or exception to this SOP.