

**SYRACUSE UNIVERSITY
HUMAN RESEARCH PROTECTION PROGRAM
STANDARD OPERATING PROCEDURES**

TITLE: COMPOSITION OF IRB COMMITTEE			DOCUMENT NUMBER: 006
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Title: COMPOSITION OF IRB COMMITTEE

1.0 Purpose:

The purpose of this Standard Operating Procedure (SOP) is to outline the requirements for composition of the membership of the Institutional Review Board (IRB) at Syracuse University (SU).

2.0 Policy:

It is the policy of the SU IRB that the composition of the IRB Committee is in accordance with Federal regulations.

Each IRB Committee must 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 not affiliated with SU (i.e. not a family member or spouse of an employee, not an active alumnus). The non-scientist and non-affiliated member may be the same individual.

3.0 References and Reference Documents:

45 CFR 46.107

34 CFR 350 and 356

OHRP IRB Guidebook

OHRP Compliance Activities: Common Findings and Guidance, July 10, 2002

SOP 021, Special Categories of Research: Children

SOP 022, Special Categories of Research: Prisoners

SOP 023, Persons with Cognitive Disabilities

4.0 Procedure:

4.1 Ex Officio and Administrative Members.

4.1.1 Ex officio members, administrative members, invited guests or expert consultants do not have voting privileges.

4.1.2 Ex officio and administrative members on the IRB Committees may include the following:

4.1.2.1 Persons who are automatically members by virtue of the position held; and

4.1.2.2 Persons necessary to the Committee by virtue of special knowledge or area of expertise (e.g., expert consultant).

4.2 Membership Selection.

4.2.1 Selections for IRB Committee member voting positions (regulate and alternate) and Chairpersons for the IRB Committees are made by the Vice President for Research and the ORIP Director based upon the specific needs of the IRB Committee.

4.2.2 The IRB Committee requests faculty volunteers each year and also seeks the advice of IRB Committee Chairs, IRB Committee Members, Department Chairs, and Deans in making its recommendations.

4.2.3 Decisions for selecting Committee members are made to assure that the IRB Committee retains diversity while maintaining regulations for required individuals to serve on the Committee.

- 4.2.4 Committee Chairs and Associate Chairs are selected as highly respected individuals from within or outside the institution, fully capable of managing the IRB and matters brought before it with fairness and impartiality.

4.3 Number of Members.

- 4.3.1 The IRB Committees are required to have a minimum of five members each, with varying backgrounds and expertise to provide complete and thorough review of research activities commonly conducted by the Institution.

4.4 Alternates.

- 4.4.1 The IRB roster shall identify the primary member(s) for whom each alternate member may substitute. To ensure an appropriate quorum is maintained, the alternate's qualifications shall be comparable to the primary member to be replaced. The IRB minutes shall document when an alternate member replaces a primary member.
- 4.4.2 When alternates substitute for a primary member, the alternate member shall have received and reviewed the same material that the primary member received or would have received. If both the primary and alternate members attend the meeting, only one may vote.
- 4.4.3 Trained alternates formally listed on the IRB roster may vote in place of an absent voting member. Alternates are assigned according to their scientific or non-scientific status as indicated on the Committee member rosters, and in accordance with the area of expertise required for adequate review. Meeting minutes must document when an alternate member replaces a voting member.

4.5 Qualifications of IRB Members.

- 4.5.2 The IRB Committee membership must be:
 - 4.5.2.1 Sufficiently qualified through the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel; and
 - 4.5.2.2 Able to ascertain the acceptability of proposed research in terms of institutional commitments, regulations, applicable law, and standards of professional conduct and practice.
- 4.5.3 Additional Qualities of IRB Committee Members and Chairpersons:
 - 4.5.3.1 Needs to be committed to the workload;
 - 4.5.3.2 Understand time commitment;
 - 4.5.3.3 Come to meetings prepared for discussion;
 - 4.5.3.4 Commitment to institutional goals for human research protections;
 - 4.5.3.5 Good communication skills;
 - 4.5.3.6 Ability to act as a facilitator;
 - 4.5.3.7 Willing to contact Investigators to discuss issues and initiate solutions prior to the meeting; and
 - 4.5.3.8 When applicable:
 - 4.5.3.8.1 Strong human participants protection expertise; or
 - 4.5.3.8.2 Research experience.

- 4.6 Composition of the membership of the IRB Committees is adequate in light of the anticipated scope and complexity of SU's research activities, the types of participant populations likely to be involved, and the size and available resources of the Institution. The IRB Administration conducts an annual review of IRB membership for composition and accuracy.

4.7 Term of Service.

- 4.7.1 Appointments for IRB Chairs, Associate Chairs, and IRB members (including alternates) are for staggered three-year terms beginning the fall of each academic year. SU has no limit on the number of terms IRB Chairs, Associate Chairs, members, and alternates may serve on the IRB. *Ex officio* members are automatically reappointed each year.

4.8 IRB Committee Members and Chair Performance Evaluations.

- 4.8.1** The ORIP Director and IRB Chair perform an ongoing assessment of the IRB Committee members based on observations made during the IRB Committee meetings, and provide feedback individually to the member to enhance and promote growth in their performance as an IRB Committee member.
- 4.8.2** The Vice President for Research and ORIP Director periodically discuss the performance of the IRB Chair to ensure the role as Chair is properly fulfilled.

4.9 Child Representative.

- 4.9.1** When reviewing proposed research on children with disabilities sponsored by the Department of Education, the SU IRB staff will make sure that that meeting will include a member with the expertise in the area of this population as described in the Department of Education's regulations at 34 CFR 350 and 356.
- 4.9.2** IRB staff screen protocols and if the protocol involves children, IRB staff will make sure that one or more individuals who are knowledgeable about or experienced in working with these individuals will be present at the meeting.
- 4.9.3** An IRB Committee considering a protocol involving children as participants should:
 - 4.9.3.1** Assess its needs for pediatric expertise among the IRB voting membership to assure that it possesses the professional competence necessary to review the specific research activities; and
 - 4.9.3.2** Consider inclusion of one or more individuals who are knowledgeable about and experienced in working with children. To fulfill this requirement, the IRB Committee may invite nonvoting individuals to assist in the review of issues which require expertise beyond, or in addition to, that available among voting IRB members. (See *SOP 021*).

4.10 Prisoner Representative.

- 4.10.1** Federal regulations require that the IRB staff screen protocols and if the protocol involves prisoners, IRB staff will ensure that at least one member present at the IRB Committee meeting shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity. (See *SOP 022*).

4.11 Persons with Cognitive Disabilities.

- 4.11.1** IRB staff screen protocols and if the protocol involves adults with cognitive disabilities or participants who may become cognitively impaired throughout the course of the research IRB staff will ensure that one or more individuals who are knowledgeable about or experienced in working with these individuals will be present at the meeting. (See *SOP 023*).

4.12 Other Special Populations

- 4.12.1** The IRB staff will screen protocols for other vulnerable populations and will ensure an IRB member or expert consultant knowledgeable about this population will be present at the meeting.

4.13 Expert Consultants.

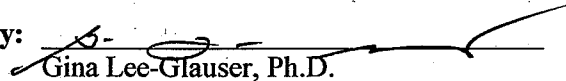
- 4.13.1** On a case-by-case basis, the IRB Committee may request review by an individual with competence in an area not represented by the Committee membership.

4.14 IRB Roster

- 4.14.1** ORIP is responsible for reporting any amendments or changes to the IRB roster to OHRP prior to the initiation of such changes.

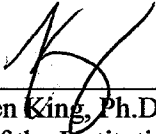
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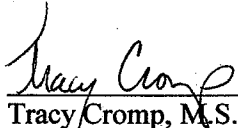


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6-14-2010
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