

<b>SOP: 201</b> <b>Effective Date: 08/21/2020</b>	<b>IRB MEMBERSHIP</b>	<b>Supersedes Document</b> <b>Dated: 07/01/2019</b>
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## **1. POLICY**

The Institutional Review Board (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 should also be able to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

Therefore, each IRB shall consist of at least five regular, voting Members. Qualified persons from multiple professions shall be considered for membership. The institution will make every effort to have as diverse as possible membership appointed to the IRB, within the scope of available expertise needed to conduct its functions.

The management of the membership of the IRB and oversight of Member appointments, IRB related activities, communications, and other administrative details are the responsibility of the Human Research Protection Program (HRPP). The IRB Executive Committee of the HRPP shall be the primary policy-making body of the HRPP with respect to IRB matters. The IRB Executive Committee will develop and implement policies related to the function of the HRPP, including SOPs, procedures, forms and implementation of federal regulations. The IRB Executive Committee shall be comprised of the IRB Chair, IRB Associate Chair, IRB Administrator, Human Research Protection Program (HRPP) Director, and a Protocol Analyst representative. The Institutional Official (IO) may participate as an ex officio member of the Executive Committee.

These policies and procedures apply to the membership of the Purdue University IRB.

## **2. PROCEDURES**

### **2.1 Membership Selection Criteria**

The Members of the IRB shall be sufficiently qualified, through experience and/or expertise, to review research proposals in terms of regulations, applicable law and standards of professional conduct and practice, and institutional commitments. Therefore, the IRB shall include persons knowledgeable in these areas.

The membership shall be diverse, so selection shall include consideration of race, gender, cultural backgrounds, clinical experience, healthcare experience and sensitivity to such issues as community attitudes to assess the research submitted for review. Those individuals involved directly in Purdue University business development may not serve as members of the IRB and may not carry out the day-to-day operations of IRB review or exemption processes.

### **2.2 Composition of the Board**

2.2.1 Regular Members: The backgrounds of the regular Members shall be varied (e.g., representing more than one area of expertise, not composed solely of males or females) in order to promote appropriate reviews of the types of

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research activities commonly reviewed by each IRB. Regular Members must include:

- (a) **Scientific Member:** The IRB must include at least one Member whose primary concerns are in the scientific area. Most IRBs include physicians and doctoral level physical, biological, or social-behavioral scientists. Such Members satisfy the requirement for at least one scientist. However, when FDA-regulated products are reviewed (such as investigational new drug studies), the convened meeting must include a licensed physician Member.
- (b) **Nonscientific Member:** The intent of the requirement for diversity of disciplines is to include Members whose main concerns are not in scientific areas. Therefore, nonscientific Members are individuals whose education, work, or interests are not solely in medical or scientific areas.
- (c) **Nonaffiliated Member:** The nonaffiliated Member(s), who can be either scientific or nonscientific reviewers, should be knowledgeable about the local community, represent the perspective of research participants, and be willing and able to discuss issues and research from that perspective. Nonaffiliated Members must not themselves be affiliated with Purdue University or be part of the immediate family of a person who holds a current affiliation with Purdue. Consideration should be given to recruiting individuals who speak for the communities from which Purdue University routinely draws its research subjects. The nonaffiliated Member(s) should not be vulnerable to intimidation by the affiliated Members on the IRB, and their knowledge and expertise should be fully utilized by the IRB.
- (d) **Representatives of special groups of subjects:** When certain types of research are reviewed, Members or consultants who are knowledgeable about the concerns of certain groups may be required. For example, if an IRB reviews research involving prisoners, an individual who can represent this group (e.g., an ex-prisoner or an individual with specialized knowledge about this group) must be included in the IRB discussion.
- (e) **IRB Chair:** The IRB Chair must be employed by Purdue University and be fully capable of providing leadership to the IRB and the matters brought before it with fairness and impartiality.
- (f) **Associate Chair:** The Associate Chair provides the Purdue HRPP with leadership and coordination of activities that contribute to the overarching goal of promoting ethical human subjects research. This

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includes (but is not limited to), presentations to faculty groups, hosting researcher seminars and assisting researchers with IRB applications. This role may also chair convened IRB meetings when the IRB Chair is unavailable.

2.2.2 Alternate Members: The IRB may formally select alternate Members to substitute for a regular Member who is unavailable. (The use of ad hoc alternates is not permitted.) The IRB Member roster should clearly indicate which regular Member(s) for whom each alternate Member is permitted to substitute. To ensure maintaining an appropriate quorum, the alternate Member's qualifications should be comparable to the regular Member to be replaced. When an alternate Member substitutes for a regular Member, the alternate Member should have received and reviewed the same material that the regular Member received or would have received.

2.2.3 Non-Member Consultants: When an IRB encounters studies involving specific topics beyond the expertise of the Members, the IRB may use a consultant with competence in such matters to assist in the review. Such consultants are not Members of the IRB and may not vote with the IRB.

## **2.3 Appointments**

Members of the IRB are appointed by the Institutional Official (IO) upon recommendation of the IRB Chair(s), HRPP Director, and IRB Administrator. Members will be solicited from Purdue University and surrounding communities. Regular Members and alternate Members are appointed using the same process.

## **2.4 Member Expectations**

### **2.4.1 Meeting Attendance**

- (a) A majority of IRB Members eligible to vote must be present at a meeting to establish quorum, therefore Scientific IRB Members are expected to attend greater than one half (1/2) of convened meetings per fiscal year (e.g., 13 of 24 scheduled meetings). A minimum attendance of one meeting must occur during the summer. Nonscientific IRB members will rotate board meeting responsibilities among the scheduled meetings. The IRB Chair is authorized to make exceptions to this expectation as appropriate in coordination with the Institutional Official.
- (b) The IRB Chair and Associate Chair are expected to attend at least 75% of regular convened IRB meetings during the one-year term.
- (c) Voting IRB Members are expected to arrive promptly and stay at convened meetings until all board business has been completed.

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- (d) IRB Members can attend meetings by telephone or other electronic means. Participating members will receive all pertinent material prior to the meeting and will be able to actively and equally participate in the discussion of all protocols.
- (e) When attendance is not possible, IRB Members must notify the IRB Administrator or designee (e.g., Protocol Analyst), allowing sufficient time in advance of the meeting to locate an alternate IRB Member to ensure a quorum.

#### 2.4.2 Knowledge of Regulations, Policies and Procedures

In order to gain and increase knowledge of the ethical, regulatory and procedure requirements for reviewing and approving research involving human subjects, IRB Members are expected to:

- (a) Be familiar with the Belmont Report and its application.
- (b) Be familiar with 45 CFR 46 and 21 CFR 56 and their application, including OHRP and FDA guidance documents.
- (c) Participate in HRPP training and ongoing education as provided by the HRPP.
- (d) Attend ongoing education for IRB Members and HRPP Staff provided by PRIM&R, AAHRPP, OHRP, or other nationally recognized bodies.
- (e) Be familiar with and abide by Purdue University HRPP policies, procedures and guidance documents governing the IRB, including all SOPs.
- (f) Mentor new IRB Members.
- (g) Serve as a resource for Investigators about Human Subjects Research.
- (h) Promote respect for the advice and counsel of the IRB in safeguarding the rights and welfare of human subjects.
- (i) IRB members (excluding Nonscientific Members) must perform a portion of expedited reviews equal to one calendar month each year. IRB members with less than one year of experience must receive sufficient in-person training by the HRPP Staff, IRB Chair or Associate Chair before performing expedited review.

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#### 2.4.3 Maintaining Confidentiality

Members are expected to respect and maintain the confidentiality of the research studies reviewed and the IRB deliberations thereon.

#### 2.4.4 Conflict of Interest Disclosure

Members are expected to disclose a real or perceived conflict with any study under review by the IRB, and not participate in the IRB review of such studies.

#### 2.4.5 Reports of Undue Influence

If a Member encounters attempt of undue influence or incidence to unduly influence a determination, the Member is expected to report to the Institutional Official or the Office of Ethics and Compliance as appropriate.

#### 2.4.6 Subcommittee or *Ad hoc* Service

Members may be asked to participate in a subcommittee of the IRB as a service on behalf of the IRB. Members may also be asked to attend meetings convened to address immediate participant risk concerns.

### 2.5 Terms

2.5.1 The IRB Chair will serve in this capacity for a term of one year. Reappointment by the IO for additional terms may occur, with input from the HRPP Director, IRB Administrator, and IRB Chair.

2.5.2 The IRB Associate Chair will serve in this capacity for a term of one year. Reappointment by the IO for additional terms may occur, with input from the HRPP Director, the IRB Administrator, and the IRB Chair.

2.5.3 IRB Members will serve on the IRB for a term of one year. Reappointment by the IO for additional terms may occur, with input from the HRPP Director, the IRB Administrator, the IRB Chair, and the IRB Member.

### 2.6 Resignations and Removals

2.6.1 If a Member resigns before the conclusion of their term, the vacancy will be filled as quickly as possible by the IO.

2.6.2 With reasonable cause, the IRB Executive Committee may recommend to the IO the removal of a Member at any time. Acting upon the recommendations of the IRB Executive Committee, the IO has the authority to remove a Member.

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2.6.3 The IRB Executive Committee may recommend to the IO removal of an IRB Chair at any time. Each voting member of the IRB Executive Committee has the authority to convene a meeting with or without the presence of the IRB Chair. Acting upon the recommendation of the IRB Executive Committee, the IO has the authority to remove the IRB Chair.

## **2.7 Compensation**

Participation by Purdue University faculty or staff, or students is considered a component of their job responsibilities as established by their supervisors. Regular voting members may be modestly compensated for the time spent in IRB-related activities. Regular Members who are not affiliated with Purdue University may receive appropriate reimbursement as consultants and miscellaneous expenses (e.g., parking).

## **2.8 Liability Insurance**

Regular and alternate Members acting consistent with their charge as IRB Members have liability insurance coverage as part of their IRB membership in their capacity as agents of Purdue University as described by University Policy.

## **2.9 Records**

The HRPP shall maintain a current list of IRB Members, along with each Member's CV or qualifications.

# **3. IRB EXECUTIVE COMMITTEE**

## **3.1 Meetings**

3.1.1 The Executive Committee shall be co-chaired by the IRB Chair, and the HRPP Director.

3.1.2 The Executive Committee shall meet no fewer than four times per academic year and more frequently as determined by need. Need shall be determined by the IRB Chairs and HRPP Director with input from the Board membership and HRPP staff. The calendar for these meetings shall be published at the beginning of the IRB term, though ad hoc meetings may occur.

3.1.3 Meeting minutes shall be recorded by a staff member designated by the HRPP Director or IRB Administrator.

3.1.4 A quorum is defined as 50% or greater of the voting membership.

3.1.5 A member present via telephone or electronic connection can be used to establish a quorum.

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- 3.1.6 Emergency meetings may be conducted via telephone conference calls, provided all members receive all relevant materials in advance of the meeting, each member can actively participate, and that all other regulatory requirements are met.
- 3.1.7 Minutes will be reviewed and approved by the co-chairs, and distributed to the committee members at the next convened meeting.
- 3.1.8 Any changes to SOPs approved at meetings will be uploaded to the HRPP website prior to the next meeting, following approval signatures from the IRB Chairs and the IO.

### **3.2 Finalizing and Distributing SOPs**

- 3.2.1 The HRPP Director or IRB Administrator will ensure that IRB Chairs and the IO sign updated and approved SOPs.
- 3.2.2 The HRPP Director or IRB Administrator will ensure that updated and approved SOPs are published on the HRPP website.

## **4. RESPONSIBILITY**

The IO is responsible for ensuring the IRB has adequate resources to identify and recruit qualified potential members. The IO appoints IRB Members for each term.

The HRPP Director is responsible for arranging for compensation as needed for consultants and nonaffiliated Members.

The IRB Administrator is responsible for recruiting and training new IRB Members in consultation with the IRB Chair and Associate Chair.

The IRB Chair and Associate Chair are responsible for mentoring and evaluating new IRB Members. The IRB Chair is responsible for management of the activities of the IRB Members relevant to meeting conduct and review of research.

IRB Members (including IRB Chair and Associate Chair) are responsible for fulfilling the IRB Member Expectations outlined in Section 2.4 above. IRB Members are also required to provide a current CV to the HRPP Office at the time of their initial appointment, and annually thereafter.

## **5. PROCESS OVERVIEW**

The IRB Chair and IRB Administrator, in consultation with the HRPP Director, may identify members of Purdue University's faculty and staff and members of the local community to serve on the IRB.

Approximately ninety (90) days prior to the end of an appointment term, the IRB Administrator will query each current Members' interest in serving for an additional term. The results of this query will be sent to the IRB Chair, HRPP Director, and IO for

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reappointment considerations and to identify the number of vacancies anticipated in the next term.

Recommendations for new appointments may also be made by any IRB Member to the IO or IRB Chair. The IRB Chair and IRB Administrator will discuss the responsibilities and time commitment of IRB membership with interested parties. If the person is interested, his or her name is submitted by the IRB Chair or designee to the IO recommending appointment of the individual to the IRB. If the IO concurs with the recommendations, he or she sends an appointment letter to the interested party, with copies to his or her department head and the IRB Administrator.

The IO and HRPP Director ensure the overall diversity of the IRB membership (e.g., gender, race, ethnicity, community affiliation, and professional experience) through establishing non-discriminatory selection methods.

The IRB Administrator, IRB Chair, and HRPP Director select new Members to replace Members who resign or otherwise leave IRB service, and recommend such Members to the IO for potential appointment.

The HRPP Support Staff maintains a roster of all regular and alternate Members, a file on all Members (to include their curriculum vitae or other evidence of professional ability), and a roster of available consultants who are eligible and qualified to review protocols and attend meetings as invited consultants.

## **6. APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46.107

21 CFR 56.107

[FDA Institutional Review Boards Frequently Asked Questions - Information Sheet](#)

## **7. REFERENCES TO OTHER APPLICABLE SOPs**

This SOP affects all other SOPs.