

IRB Membership and Responsibilities Policy

1.0 Purpose

The purpose of this policy is to define the composition of the Wright State University Institutional Review Board (IRB) to ensure compliance with federal regulations 45 CFR 46.107, 46.108(a)(2) and 21 CFR 56.107. It is also to describe the procedures for identifying and managing IRB member (includes alternates, *Ex officio* and consultants) conflicts of interest related to the IRB review process.

2.0 Scope

This policy applies to all individuals involved in the review of human subject research at Wright State University, including but not limited to, all IRB members, the IRB Chair, Human Research Protection Program (HRPP) staff members and consultants to the IRB.

3.0 Definitions

- 3.1 **Alternate IRB Member** means an individual appointed to the IRB to serve in the same capacity as the specific IRB member(s) for whom the alternate is named, who substitutes for the member at convened meetings when the member is not in attendance. If both the member and alternate member are present at a convened meeting, only one will count for quorum and will be allowed to vote.
- 3.2 **Director** means a member of the HRPP Office who directs, manages, implements, and administers policies and procedures related to research involving human subjects. The Director provides for all compliance and regulatory functions of the IRB ensuring adherence to all federal, state, and local regulations and policies governing research involving human subjects including the Belmont Report and the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations.
- 3.3 **Financial Conflict of Interest** means a monetary interest of an individual (or his/her immediate family) in the design, conduct, or reporting of the human subject research or other interest that competes with an IRB member's (or consultant's) obligation to protect research participants and potentially

compromises the objectivity and credibility of the research review process.

- 3.4 **Human Research Protection Program (HRPP)** means a multi-tiered program involving the University administration, the Wright State Institutional Official, the Wright State Institutional Review Board, HRPP Office, other research administrative and compliance offices, and investigators.
- 3.5 **Institutional Official (IO)** means a high-level official who is the signatory on the Federalwide Assurance (FWA) filed with OHRP and has the authority to represent the institution. The Vice Provost for Research and Innovation serves as the IO for Wright State University.
- 3.6 **Institutional Review Board (IRB)** means a committee established to review and approve research involving human subjects. The purpose of the IRB is to ensure that all human subject research be conducted in accordance with all federal, institutional, and ethical guidelines.
- 3.7 **IRB Member** means an individual appointed as a member of the IRB with the right to act as an expedited reviewer and the right to vote and count in determining quorum at a convened meeting.
- 3.8 **Non-affiliated IRB member** means an individual who is not affiliated with Wright State and who is not part of the immediate family of someone who is affiliated with Wright State. This individual must not have or had have an employment or other relationship with Wright State.
- 3.9 **Non-financial conflict of interest** means an interest other than monetary of an individual (or his/her immediate family) in the design, conduct, or reporting of the human subject research or other interest that competes with an IRB member's (or consultant's) obligation to protect research participants and potentially compromises the objectivity and credibility of the research review process.
- 3.10 **Non-scientist member** means an individual appointed by the IRB who can review research activities from the viewpoint of someone outside the scientific or scholarly discipline of the IRB on which he/she serves due to his/her training, background or occupation.

- 3.11 **Office of Human Research Protections (OHRP)** means the administrative agency that oversees the United States' system for protecting volunteers in research conducted or supported by the U.S. Department of Health and Human Services (DHHS).
- 3.12 **Principal Investigator (PI)** means the primary individual responsible for the preparation, conduct, and administration of a human subject research study.
- 3.13 **Quorum** means the majority of the voting members. In the case of the Institutional Review Board (IRB), a quorum will consist of at least 51% of the voting IRB members and must include at least one non-scientific member. All members present have equal voting power. At meetings of the IRB, a quorum must be established and maintained throughout the entire meeting. A member with a conflict of interest cannot contribute to a quorum. For Food and Drug Administration-regulated research, a licensed physician must be present during the review, deliberation and voting to satisfy the quorum requirement under Code of Federal Regulations Title 21 CFR 56.108(c).

4.0 **Policy**

4.1 Membership

The IRB must have at least five members, with varying backgrounds, experiences, and expertise to promote complete and adequate review of research activities commonly conducted by the University. IRB membership must be sufficiently qualified through experience and expertise of its members to represent and consider issues such as race, gender, community attitudes and cultural backgrounds to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition, the IRB must be able to ascertain the acceptability of proposed research in terms of institutional commitments/resources, regulation, local law, and standards of professional conduct and practice.

If the IRB regularly reviews research that involves a vulnerable category of subjects, such as prisoners, children, pregnant women, or physically or decisionally impaired persons, the IRB membership will include individuals who are knowledgeable about and experienced in working with those subjects.

Every effort will be made to ensure that the IRB does not consist entirely of men or entirely of women or consist of members of one profession. It must include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. The IRB also must 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. A licensed physician is required for review of any FDA-regulated submissions.

Because the IRB acts as an IRB of Record for the Dayton Veterans Affairs Medical Center (VAMC), membership will include at least two voting members who are VAMC employees. Normally, at least one voting VAMC IRB member or their alternate will be present for the full board review VAMC research.

When the IRB reviews Premier Health research at a convened meeting, the voting nurse researcher member or his/her alternate must be present and take part in the review.

Ex Officio members are non-voting members who serve as liaisons to ensure coordination among other research administrative units and affiliated institutions. Examples include but are not limited to the Wright State Research Compliance Director, Wright State General Counsel and Premier/VAMC research administration officials.

The IRB may invite individuals (i.e., consultants) with competencies 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 at convened meetings (see *Convened Institutional Review Board Review Policy* for additional information).

Liability coverage for IRB members acting within the proper course and scope of their IRB duties is provided through Wright State's liability insurance coverage, whether or not the IRB member is an employee of Wright State University.

4.2 Alternate Members

Alternate members must have qualifications comparable to the applicable

regular voting members and may be designated on the roster as an alternate for more than one IRB member. Alternate members can replace IRB members at convened meetings and can act as expedited reviewers. Alternate members attending a meeting or conducting protocol review have all the authority of regular members. If the regular member and the alternate member substituting for that meeting attend the same convened meeting, only one may vote on each agenda item.

4.3 Conflicts of Interest

IRB members with a conflicting interest cannot participate in the review of human subject research related to that conflict (which includes, but is not limited to, exemption determinations, expedited or full board initial review, continuing review, and review of unanticipated problems or non-compliance cases) except to provide information requested by the IRB. These conflicts may take the form of financial interests or be based on the IRB member's responsibilities or relationships.

IRB members must inform the IRB Chair or Director of any conflict of interest that may arise in the review of research for the IRB. A conflict of interest depends on the situation, and not on the character or actions of the individual.

5.0 Procedures

5.1 Member Appointment and Credentialing

All IRB members are formally appointed in writing by the Institutional Official (IO). Normally, the IO will consult with the IRB Chair and Director as part of the decision process. Each member is appointed for a five-year renewable term. Before acting as a voting IRB member, a new member (both regular and alternate) must complete the following prior to conducting any independent reviews:

- Observe at least three convened meetings with mentorship by a current voting member

- Complete IRB Member Training Requirements (e.g., PRIM&R Ethical Research Oversight Course (EROC) or Collaborative Institutional Training Initiative (CITI) equivalent)
- Complete IRB Office training sessions regarding review procedures and use of electronic submission system
- Review at least three studies that qualify for expedited review in tandem with a current voting member
- Complete confidentiality agreement
- Provide Director with a copy of current curriculum vitae (CV), and
- Complete annual Significant Financial Interest Disclosure form via the electronic system and the CITI COI course.

5.2 Member Evaluation

The Director and IRB Chair will compare the composition of the committee with the types of research being conducted to confirm that there is appropriate representation and expertise annually.

At least once every five years, the IRB Chair and Director will evaluate and report to the IO each member's attendance, contribution to full and expedited review processes, and status of the following continuing credentialing requirements:

- Complete the CITI COI Refresher Course once every four years.
- Complete other required member refresher training via CITI every three years
- Review continuing education articles/materials provided at convened meetings and participate in related discussions
- Attend at least 75 percent of convened meetings (alternates are only required to attend 25 percent of convened meetings)
- Provide updated CV upon request, and
- Review new or revised IRB policies, guidance documents and other reference materials found on IRB's website.

5.3 Resignations and Other Membership Changes

Wright State will fill IRB membership vacancies as soon as possible. The Director will solicit recommendations from a variety of sources and make recommendations for replacement of members who resign. Voting members

who wish to resign/retire from the IRB are asked to give at least two months' notice.

The IO makes all final IRB member appointments and has the authority to remove members who do not meet membership responsibilities (See Sections 5.1 and 5.2).

5.4 OHRP/FDA Registration and Membership Roster

The Director or his/her designee is responsible for completing the OHRP/FDA registration forms in accordance with federal requirements and for updating IRB registration in a timely manner. He/she is also responsible for maintaining a membership roster that can be used to determine quorum at convened meetings. The IRB Roster must contain the following information:

- Member Name
- Earned Degree
- Scientist/Non-Scientist Designation
- Experience/Specialization
- Affiliated/Non-Affiliated Status, and
- Voting Member Alternate if Alternate Member.

5.5 Annual Significant Financial Interest Disclosure

All individuals covered by this policy must submit a research significant financial interest disclosure form annually via Wright State's electronic submission system. This form must be updated within 30 days of any reportable changes throughout the year, in addition to the annual disclosure.

Disclosable significant financial interests (SFIs) are defined by Wright State's *Research Conflict of Interest and Financial Disclosure Policy* and include an individual's (including spouse and/or dependent children's) financial interests that may be or appear to be related to his/her institutional responsibilities (e.g., IRB Membership, research, teaching).

5.6 Non-Financial Conflicts of Interest

Certain types of roles and relationships can also constitute conflicts of interest. The following are examples of potential non-financial conflicts of interest:

- Participation in the research by the IRB member or his/her spouse or dependent child.
- Supervision of the research by the IRB member or his/her spouse or dependent child. For example, the IRB member is the Principal Investigator's department chairperson.
- Any other reason an IRB member believes he/she cannot provide an independent review.

5.7 Screening of Significant Financial Interests Prior to IRB Review

The Director or HRPP staff member will review any significant financial interests (SFIs) disclosed by IRB members and the IRB Chair on a regular basis. He/she will determine whether any disclosed SFIs are sufficiently related to a submission such that they represent a potential financial conflict of interest. An IRB member or Chair will not knowingly be assigned as a reviewer for any protocol (full and expedited review) in which he/she has a real or perceived financial conflict of interest.

If the IRB Chair has a related SFI, an HRPP staff member will assign another IRB member(s) to act as the study submission reviewer(s) and request that Vice Chair temporarily assume the Chair's duties so that the IRB Chair will not be involved in the review process for that submission.

The IRB Chair will be responsible for managing any HRPP staff member's potential conflicts of interest. A HRPP staff member or consultant to the IRB will not be involved with the review of a submission for which he/she has a conflict of interest.

5.8 Screening of Non-Financial Conflicts of Interest

The IRB Chair and/or HRPP staff member will screen each submission to determine whether an IRB member(s) has a conflict due to being an investigator on the protocol, having supervisory responsibility or other conflicting relationship with the research. This information will be utilized to assign

appropriate non-conflicted reviewers for each submission, as well as manage recusals at convened meetings (see Section 5.5).

It is ultimately the responsibility of the IRB member/alternate/consultant to bring any conflict of interest to the attention of the IRB Chair or Director. See *Convened Institutional Review Board Review Policy* for more information about procedures to identify, address and document conflicts at convened meetings.

6.0 Records

All records related to this process will be stored and maintained in accordance with any Wright State policy, federal regulations and sponsor requirements associated with activity under review.

7.0 References

- 7.1 45 CFR 46.115(a)(5)
- 7.2 45 CFR 46.107
- 7.3 45 CFR 46.108(a)(2)
- 7.4 21 CFR 55.107
- 7.5 21 CFR 56.115(a)(5) & 56.106
- 7.6 45 CFR 46 Subpart E
- 7.7 US Department of Health and Human Services (HHS) Registration of an IRB
- 7.8 VA Handbook
- 7.9 38 CFR 16