THE OHIO STATE UNIVERSITY

IRB COMPOSITION AND IRB MEMBER ROLES AND RESPONSIBILITIES

1. Overview

Each IRB must be appropriately constituted for the volume and types of human research to be reviewed, in accordance with federal regulations. The IRBs will include members with diverse experience and expertise to assure the professional competence necessary to review the university's research, as well as knowledge of community attitudes and training in protecting the rights and welfare of human subjects. The purpose of this policy is to describe the membership and quorum requirements for The Ohio State University IRBs.

2. Definitions

Affiliated: IRB membership status designating association with the university. *Note: A member (or alternate) is considered to be affiliated if he/she or a member of his/her immediate family is a current or past (within the last 2 years): employee (full or part-time); clinical, adjunct, or visiting faculty member or instructor; paid or unpaid member of a university governing panel or board (not including the IRBs); healthcare provider holding credentials to practice at Ohio State; volunteer working at the university (unrelated to IRB service); or university consultant or advisor (paid or unpaid). An emeritus faculty or retired staff member is also considered to be affiliated if he/she has been retired or involved in paid or unpaid university activities (including research or service) within the last 2 years. Current undergraduate, graduate, and postdoctoral students are also considered to be affiliated, as described by HRPP policy.*

Alternate: 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. *Note: IRB members and alternates have equal responsibilities in terms of required education, service, and participation.* (See below for additional information about alternates.)

Non-Scientist: An individual appointed to the IRB who (due to training, background, and/or occupation) is inclined to view research activities from the standpoint of someone outside the scientific or scholarly discipline of the IRB on which he/she serves.

3. IRB Composition

A. In appointing IRB members, the Institutional Official (IO) and/or Vice President for Research will ensure that all of the following conditions are met for the university IRBs:

- IRB members will have varying backgrounds, experience, expertise, and professional competence as necessary to promote complete and adequate review of research activities commonly conducted by Ohio State
- Each IRB will be sufficiently qualified through the experience, expertise, and diversity of its members, including considerations of race, gender, cultural backgrounds, and sensitivity to issues such as community attitudes, to promote

respect for its advice and counsel in safeguarding the rights and welfare of human subjects

- Each IRB will include persons knowledgeable about institutional commitments and regulations, applicable laws, and standards of professional conduct and practices
- If the IRB regularly reviews research that involves a category of participants that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, the IO will appoint one or more individuals who are knowledgeable about and experienced in working with these categories of participants
- Each IRB will consist of at least five members
- Each IRB will include at least one member whose primary concerns are in scientific areas
- Each IRB will include at least one member whose primary concerns are in nonscientific areas, at least one member who represents the perspective of research participants, and at least one member who is not otherwise affiliated with Ohio State and who is not part of the immediate family of a person affiliated with Ohio State.

  Note: In many cases, the same member will satisfy the three roles. The IRB may, on occasion, meet without representation of the unaffiliated member; however, this should be the exception. Attendance of the unaffiliated member and the member who represents the perspective of subjects at convened meetings will be monitored and assessed through documentation in the minutes (e.g. minutes indicate attendance at greater than 50% of meetings).

B. For additional requirements for review of research involving prisoners, see HRPP policy [Research Involving Prisoners].

C. The IRB may invite individuals with competence in special areas to assist in the review of protocols that require expertise beyond or in addition to that available on the IRB. These individuals (consultants) may not vote with the IRB.

D. Other individuals also attend convened meetings as necessary. These individuals advise the IRB on the acceptability of proposed research in terms of regulatory requirements, institutional commitments, applicable laws, and standards of professional practices and conduct. Examples include, but are not limited to, representatives from the Office of Responsible Research Practices, Office of Sponsored Programs, Office of Research Compliance, and Office of Legal Affairs. Note: Individuals responsible for business development or grants and contracts (e.g., Industry Liaison Office, Office of Sponsored Programs) do not serve as IRB members or alternates.

E. All IRB members, alternates, and ORRP staff receive human subjects protections education related to federal regulations and guidance, HRPP policies and procedures, and IRB review processes. Minimally, initial training in human subjects protection, with continuing education every three years is required (e.g., completion of Collaborative Institutional Training Initiative modules). IRB members and ORRP staff also receive

additional education/new information via newsletters, email announcements, website postings, webinars, and in-person training sessions.

4. Quorum

A. ORRP staff attending IRB meetings are responsible for determining that meetings are appropriately convened before the discussion and vote for each review. For convened IRB review, a quorum is defined as follows:

- The necessary number (i.e., more than half) of the IRB members listed on the membership roster are present
- At least one member is present whose primary concerns are in nonscientific areas
- At least one member is present whose primary concerns are in scientific areas
- For FDA-regulated research, a member is present who is a licensed physician
- For research involving a category of participants vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, a member is present representing the vulnerable population's interests.

Note: A member serving as a prisoner representative on the Cancer and Biomedical Sciences IRBs will only count toward quorum when he/she is in attendance and reviewing research involving prisoners.

B. If both an IRB member and his/her respective alternate(s) are present, only one may vote and be counted toward quorum.

C. Comments from members unable to attend a meeting that have been provided in advance (e.g., by fax or e-mail) may be considered by the attending IRB members, but may not be counted as votes or toward the quorum for convened meetings.

D. Any member may participate by teleconference or videoconference, provided he/she has received all materials and can actively and equally participate in the discussion.

E. Assuming all applicable composition requirements are satisfied, the number of IRB members necessary for a quorum is calculated by dividing the number of members in half and "rounding up" when there is an odd number of members or "adding one" for an even number. For example:

- If an IRB has 15 members, the quorum is 8.
- If an IRB has 20 members, the quorum is 11.

F. If quorum is not met, then IRB voting cannot take place; and the items on the agenda will be tabled until the next convened IRB meeting.

G. If quorum is lost during a convened meeting (e.g., due to a member leaving the meeting), then no further voting can take place; and the remaining items on the agenda will be tabled until quorum is restored or the next convened IRB meeting.

H. ORRP staff attending IRB meetings are responsible for recording the attendance of members as they enter and leave the room. If quorum is lost, ORRP staff will notify the

IRB Chair or Vice Chair that no further actions can be taken until/unless quorum is restored.

I. IRB members with potential conflicts of interest must leave the room before discussion of the research, except to provide information requested by the IRB. Members with potential conflicts of interest may not be present for the vote and are not counted toward quorum for review of the research for which the potential conflict exists, in accordance with HRPP policy [IRB Member and Consultant Conflict of Interest].

5. IRB Membership Roles and Responsibilities

A. IRB Chairs

The Chairs are appointed by the Institutional Official and/or Vice President for Research and selected based on experience and expertise from among current and former IRB members. Each IRB Chair serves a three-year term of service (with renewable terms of one to three years). The IRB Chairs have primary responsibility for the following:

- Providing leadership to the IRB to help ensure the rights and welfare of human subjects participating in research reviewed by the IRB
- Conducting convened meetings and reviewing and approving the minutes documenting IRB discussions and findings
- Leading discussions with investigators and/or administrators to resolve controversial and/or procedural matters relating to research approval and conduct
- Annually completing the electronic *Financial Conflict of Interest Form* and disclosing any potential conflicts prior to IRB review of the research for which a conflict may exist
- Managing conflicts of interest by ensuring that IRB members with conflicts are not present for review of research for which a conflict may exist
- Maintaining confidentiality of IRB-related information in accordance with the terms and conditions of the university's *IRB Member Confidentiality Agreement*
- Administering Board decisions and maintaining the independence of the IRB
- Signing correspondence communicating and documenting IRB decisions
- Reviewing and approving research by expedited procedures
- Participating in the development of meeting agendas, policies, procedures, and educational efforts to support the human research protection program
- Maintaining a current knowledge of and assuring compliance with relevant regulations, laws, and policies related to the protection of human subjects
- Regularly consulting with the Office of Responsible Research Practices Director and staff regarding IRB issues
- Assisting with investigations and review of alleged noncompliance with human subjects protections requirements as specified by HRPP policy [Noncompliance]
- Serving as a member of the IRB Policy Committee and participating in the development of policies, procedures, and institutional efforts to promote a culture of shared responsibility for the safety and welfare of research participants.

B. Vice Chairs

1. The Vice Chair of each IRB is appointed by the Institutional Official and/or Vice President for Research and selected based on experience and expertise from among current and former IRB members. Each Vice Chair serves a three-year term of service (with renewable terms of one to three years).

2. The Vice Chairs support the role and responsibilities of the IRB Chair. The Vice Chairs attend IRB meetings and chair convened meetings when required. The Vice Chairs assume duties as delegated by the Chairs.

3. Vice Chairs are members of the IRB Policy Committee and work with Chairs, IRB members, and ORRP staff to develop and implement policies and procedures to assure the efficiency and effectiveness of the human research protection program.

C. IRB Members

Each IRB member is appointed by the Institutional Official and/or Vice President for Research and serves a three-year term of service (with renewable terms of one to three years). IRB member responsibilities include all of the following:

- Attending IRB meetings (see attendance requirements for the unaffiliated member and the member who represents the perspective of participants in Section 3. A. above) and actively participating in the review of research, unless arrangements have been made for the alternate's attendance
- Completing initial training in human subjects protection for IRB members prior to voting on any research, with continuing education every three years and as provided
- Understanding and applying the principles of the Belmont Report and the federal regulations related to the protection of human subjects
- Providing timely written comments on research undergoing IRB review, when required
- Annually completing the electronic *Financial Conflict of Interest Form* and disclosing any potential conflicts prior to IRB review of the research for which a conflict may exist
- Maintaining confidentiality of IRB-related information in accordance with the terms and conditions of the university's *IRB Member Confidentiality Agreement*
- Maintaining a current knowledge of and assuring compliance with relevant regulations, laws, and policies related to the protection of human subjects
- Working with investigators to resolve matters relating to research approval and participating in educational efforts for investigators, research staff, and new IRB members
- Participating in the discussion of issues affecting the human research protection program and contributing to policy development, as appropriate
- Reviewing and approving research by expedited procedures, when designated by the IRB Chair to perform this review.

D. Alternates

1. Federal regulations allow organizations to appoint an alternate(s) to substitute for an IRB member(s) who is unable to attend so that IRB business may move forward in a timely manner. Alternates are appointed by the same process and for the same length of time as IRB members.

2. IRB alternates function as regular board members when they are in attendance. An alternate may substitute for the primary IRB member for an entire meeting or at any time during a meeting. Alternates and IRB members have equal responsibilities (i.e., "job-share") in terms of required education, service and time commitments, and participation.

3. Each alternate member is paired with one or more regular members with comparable experience and expertise, as possible. The IRB roster identifies the primary member(s) for whom each alternate may substitute. Minimally, alternates and members are paired by scientific "class," as physician scientists (when applicable), other scientists, and non-scientists. The IRB roster will identify the member(s) for whom each alternate can substitute.

4. When an alternate substitutes for a regular IRB member, the alternate receives and reviews the same materials that the regular member received (or would have received), and IRB minutes document that an alternate replaced a primary member.

6. Consultants

A. For research that requires expertise beyond or in addition to that available on the IRBs (including application of laws outside the state of Ohio), or involves a vulnerable population where no IRB member knowledgeable about or experienced in working with these participants will be present at the meeting, one of the following will occur:

- ORRP staff may identify the need for review by a consultant during the screening of a protocol submission. The ORRP staff member will invite an individual with the necessary expertise to serve as a consultant and assist the IRB in its review.
- The primary reviewers or IRB membership may identify the need for a consultant during their review. The primary reviewer(s) will work with an ORRP staff member and/or IRB Chair to invite an individual with the necessary expertise to serve as a consultant and assist the IRB in its review.

B. Consultants with potential conflicts of interest may not provide information to the IRB. Conflicts will be identified as described by HRPP policy [IRB Member and Consultant Conflict of Interest].

C. The use of a consultant and the result of the consultant's review will be shared with the IRB by either having the consultant attend and present to the convened IRB or by having the consultant provide a written report to the IRB.

- If the consultant presents at a convened meeting, the IRB minutes will document key information provided by the consultant. The consultant will not vote with the IRB.

- If the consultant provides a written report, the report will be included in the protocol records.

7. Membership Rosters

A. Rosters for each IRB contain the following information for each member and alternate:

- Name
- Earned degree(s)
- Chief anticipated contribution (board certifications, licenses, etc.)
- Special representation
- Scientist status (physician, other, or non-scientist)
- Affiliation (yes or no)
- Employment or other relationship with the university (e.g., paid or unpaid member of a university governing panel or board member (not including the IRBs), consultant, hospital volunteer, etc.).

B. Information for alternates includes also the member(s) for whom the alternate may substitute. Prisoner representatives are listed as "ad hoc" members on the Cancer and Biomedical Sciences IRB rosters and will only count toward quorum when he/she is in attendance and reviewing studies involving prisoners.

8. Review of IRB Composition and Performance

A. The composition of the IRBs is reviewed at least annually by the IRB Chairs and ORRP staff to determine if adjustment of the membership or composition is necessary to meet regulatory and organizational requirements. IRB members are notified in writing by the Institutional Official when their services are requested or if they are no longer needed to serve.

B. On an annual basis the IRB Chairs, with input from ORRP staff, evaluate individual IRB member performance in terms of attendance, timeliness, and overall review quality. Feedback is provided to IRB members by the Chair or designee. Recognition letters based on length/quality of service are also provided to members' Department Chairs (or Signatory Officials), as applicable.

C. The Institutional Official, ORRP Director, or designee, with input from IRB members and ORRP staff, evaluates IRB Chairs' and Vice Chairs' performance and provides feedback on an annual basis. The Institutional Official and/or Vice President for Research are responsible for addressing performance issues with the IRB Chairs/Vice Chairs and for selecting new Chairs and Vice Chairs when necessary. Recognition letters based on length/quality of service are also provided to IRB Chairs' and Vice Chairs' Department Chairs (or Signatory Officials), as applicable.

D. ORRP staff will promptly update the roster when changes in IRB membership are made. Updated rosters are posted on the ORRP website.

9. Applicable Regulations/Guidance

21 CFR 56.107, 21 CFR 56.108, 21 CFR 56.115, 45 CFR 46.103, 45 CFR 46.107, 45 CFR 46.108, FDA Information Sheets: “A Self-Evaluation Checklist for IRBs,” FDA Information Sheets: Frequently Asked Questions: “IRB Membership,” and “Written IRB Procedures: OHRP Guidance” (07/01/2011)

10. History

Issued: 07/21/2008
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