SOP		
Department	**Title**	**Dates**
Research Integrity and Protection	IRB Membership and Management	Effective: 10/25/2017
		Approved: 3/9/2017
Policy ID		Last Revised: 7/29/19
IRB-SOP-801		Expiration: n/a

PURPOSE

This procedure is to describe the role and qualifications of Ascension Wisconsin IRB members, as well as the expectations, management and evaluation of IRB members.

SCOPE

This policy applies to all IRBs established within Ascension Wisconsin and all members who serve on the IRBs.

DEFINITIONS

Unaffiliated: An IRB member who is not otherwise affiliated with the institution or trial site, and who is not the immediate family member for a person with such affiliation.

Scientific: An IRB member whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist.

Non-Scientific: IRB member who has little or no scientific or medical training or experience and whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline.

PROCEDURES

1. **IRB Composition**
   - **1.1.** Each IRB will consist of at least five voting members, including the Chair(s), and may include alternate members.
   - **1.2.** IRBs will include at least one member who is unaffiliated with the institution.
   - **1.3.** IRBs will include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas.
   - **1.4.** When reviewing FDA-regulated studies, the IRB must include at least one physician.
   - **1.5.** The IRB(s) will be sufficiently qualified through the experience, expertise and diversity of its members, to promote respect for its advice and counsel in safeguarding the rights and welfare of human research subjects including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes or considerations for certain populations.
   - **1.6.** For projects supported by the U.S. Dept. of HHS's National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) that "purposefully requires" inclusion of children with disabilities or individuals with mental disabilities, the IRB must include at least one member who is primarily concerned with the welfare of these research subjects (refer to 34 CFR 350 and 34 CFR 356).

2. Membership Roles

2.1. IRB Chairs

2.1.1. Each IRB will have one Chair and may have a Co-Chair, or multiple Vice-Chairs (referred to collectively here as "Chair" or "Chairs")

2.1.2. The Chair must hold a terminal degree (e.g. M.D., D.O., or Ph.D.) and be proficient in clinical research; and be of sound and ethical character and reputation, without conflicts of interest that would curtail their ability to serve objectively and according to the mission of the IRB as defined in applicable laws, regulations, and policies. At any time, at least one Chair must be an Ascension Wisconsin associate or associate of an affiliated institution in good standing.

2.1.3. The Institutional Official will evaluate the performance of the Chair of the IRB, as deemed necessary, and may consult with others such as the Hospital/Medical Group President or IRB staff.

2.2. Primary Members

2.2.1. Primary members are those listed on the IRB roster that fulfils the IRB composition requirements outlined above.

2.3. Alternate Members

2.3.1. Each IRB maintains a roster of trained alternates who may vote in place of an absent voting member.

2.3.2. The alternate member will have similar expertise as the regular committee member for whom s/he is serving as a replacement.

2.3.3. The alternate member will assume all of the responsibilities of the committee member for whom s/he is serving as a replacement.

2.3.4. Alternate members may attend IRB meetings without serving as a replacement for a regular committee member; however, in this capacity, the alternate member may not count towards quorum when voting for the final approval decisions of the committee.

2.3.5. IRB minutes will document if a member present at the meeting is an alternate as well as the IRB member for whom the alternate is substituting.

3. Appointment

3.1. Members, including the Chair(s), are appointed for a three-year term with renewable terms for an undefined period of time. As terms end and vacancies are established, the goals of both consistency of members and the need for new ideas are taken into consideration.

3.2. The Institutional Official or designee appoints IRB primary and alternate members and IRB Chairs. The Institutional Official will consider the recommendations of the IRB Chair and IRB staff. Copies of the CV and/or resume will be submitted to the IRB office for review.

3.3. IRB staff oversee the management of member appointments, IRB related activities, communications and other administrative details.

3.4. Members receive notification of appointment from the Institutional Official or designee, notifying them of the Board and role in which they will serve.

4. Desginating Members as Reviewers

4.1. The IRB chair may designate IRB members who can conduct non-committee reviews by notifiying staff.

4.2. RI&P staff verify the experience of IRB member and update the Roster tracking log to indicate the designation.

5. IRB Membership Rosters

5.1. RI&P staff maintains the current membership roster for each IRB and IRB rosters will be posted on the website or by contacting the IRB office.

5.2. Membership rosters are revised by IRB staff to provide updates to include new members, current members extending their membership, members moving from one IRB to another or serving on multiple IRBs, members or alternate members that are resigning or are no longer eligible for membership. Roster versions are recorded on the Roster Tracking Log.

5.3. The IRB membership roster will include the following information and will be used to determine relevant expertise:

- Names of members
- Earned degrees
- Representative capacities
- Scientific/nonscientific status
- Affiliated/unaffiliated status, including any employment or other relationship between members and the Institution
- Indications of experience sufficient to describe each IRB member's chief anticipated contributions
- Membership status (member, alternate, chair, etc.)
- Alternate members including the primary members or class of primary members for whom each alternate can substitute
- Indication if the member is a designated reveiwer

5. Responsibilities of IRB Members

5.1. General Responsibilities of all IRB Members include the following:

- Review all protocol materials prior to the meeting and comment on all aspects of proposed research and each type of member brings a specific perspective to the review process.
- Attend at least 70% of IRB meetings in person, unless exigent circumstances prevent such attendance on an occasional basis; reporting promptly at the designated time that the meeting convenes; and remaining in attendance at the meeting until the full agenda has been addressed; alternate members may attend less frequently, as required.
- Actively participate in IRB deliberations concerning issues inherent to proposed research studies and related informed consent documents, and making recommendations for reducing risk and improving the informed consent process and otherwise for improving human subject protections.
- Actively pursue and maintain familiarity with the federal regulations pertaining to human subject protection, including reference materials provided during educational discussion at meetings.
- Recommending improvements to IRB policies and procedures so as to enhance the IRB review process and/or human subject protections.
- Informing the IRB Chair or an IRB Vice Chair of human subject research noncompliance problems or ethical issues of which they become aware.
- Conforming, at all times, their behavior to be within legal and ethical principles accepted by the IRB; including, but not limited to, maintaining confidentiality/non-disclosure of human subject research submitted for IRB review and approval, and good faith participation in IRB deliberations without appearance of discrimination or conflict-of-interest.

5.2. Responsibilities of IRB Members Designated Reviewers

In addition to the responsibilities outlined above, responsibilities of those designated as reviewers include:

- Reviewing research study proposals and evaluating them from the perspective of the regulatory criteria for approval addressed under 45 CFR 46.111, 21 CFR 56.111 (if applicable); and any other relevant ethical, scientific or compliance considerations.

- Reviewing informed consent documents and evaluating them from the perspective of addressing the required and additional elements of informed consent addressed under 45 CFR 46.116, 21 CFR 50.20 (if applicable) and any other relevant ethical or compliance considerations.
- Providing written evaluations of the research protocol and informed consent document(s) to the IRB Office staff either on paper or through the electronic submission system in within the timeframe assigned.
- Utilizing the IRB Reviewer Checklist as a guide when reviewing protocol submissions. Basing their review and approval decisions for industry-sponsored clinical trials on the information presented in the sponsor's clinical protocol and investigator's brochure and IRB research application.
- Ensuring that for federally-supported research requiring full board IRB review that the IRB research application is essentially consistent with the corresponding federal grant application.

5.3. Additional Responsibilities of the IRB Chair, Co- Chair or Vice Chair
In addition to IRB member responsibilities, the responsibilities of the Chair(s) include the following:

- Primary responsibility for conducting IRB meetings
- Designate IRB member reviewers to complete non-committee reviews as appropriate
- Ensure operation of the IRB within all applicable regulatory requirements
- Advise and consult with investigators regarding human subject protection issues and IRB requirements
- Participate in noncompliance investigations
- Contribute to the development of policies and procedures
- Serve as a liaison between the IRB, investigators, Institutional Official/CMO, Research Education and Quality Management and others, as needed
- Work with the Director on member evaluation and to resolve administrative issues of concern

6. Evaluation of the IRB

6.1. IRB Chairs and senior IRB staff will meet as needed to discuss the conduct of IRB Committee meetings and the performance of IRB membership. Research Education and Quality Management may provide IRB staff comments on review quality. If concerns are identified, the IRB Chair(s) will address these with the individual committee member and then provide necessary guidance materials or educational sessions.

6.2. Any general concerns about how the committee is functioning will be brought to the attention of the full IRB whenever and as frequently as necessary.

6.3. Attendance of the members will be monitored IRB staff. Any issues that arise related to non-attendance will be discussed with the IRB Chair to determine whether action is necessary.

6.4. Each member will be given an annual letter that describes performance as satisfactory or requiring attention. The letter will include metrics on attendance and volume of IRB assignments for the member and members will have the opportunity to meet informally with the IRB Chair(s).

7. Compensation/Expense Reimbursement

IRB members will not receive compensation for their IRB participation. IRB members may be reimbursed for travel-related expenses, per institution policy.

8. Resignation and Termination of IRB Members

8.1. Resignation of IRB membership status, based on the wishes of the IRB member, will be submitted to the Institutional Official and copied to the IRB Chair and, where applicable, the member's department chair or center/institute director.

8.2. IRB Membership status may be terminated by the IRB Chair due to failure to attend and/or otherwise actively participate in IRB functions. Termination of any individual from IRB membership will be reported to the Institutional Official to include a written justification for the termination.

8.3. IRB staff will maintain documentation in the IRB file.

REFERNCES

45 CFR 46.107
21 CFR 56.107

RELATED MATERIAL

None

REVISION HISTORY

Version #	Date Revised	Reason for/Brief Description of Change	Revised By
01	4/11/2017	New- Initial Integration Update	J. Blundon
02	11/21/2017	4.2. Addition of reference to roster tracking log	J. Blundon
03	10/17/18	Add new section (4) to clarify process for designating IRB members for non-committee review; clarifications throughout for consistency with update	J. Blundon-Kirchen
04	7/29/2019	2.1.2. Addition that at least one Chair, not all, must be an associate or affiliate	J. Kirchen