



## IRB Membership

### 1. SCOPE

- 1.1. System-Wide

### 2. DEFINITIONS & EXPLANATIONS OF TERMS

- 2.1. None

### 3. RESOURCE GUIDE BODY

This document outlines the composition of and appointing process for the Marshfield Clinic Research Foundation IRB (MCRF IRB), term limits and compensation, and the orientation process for new members.

#### 3.1. Federal Regulations

- a. Department of Health & Human Services regulations (45 CFR 46.107) and Food and Drug Administration regulations (21 CFR 56.107) set forth IRB membership requirements. They require that an IRB:

- have at least five members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution;
- be sufficiently qualified through the experience and expertise of its members, as well as the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects;
- include members who are able to ascertain the acceptability of proposed research in terms of institutional commitment and regulations, applicable law, and standards of professional conduct and practice;
- which regularly reviews research that involves a vulnerable category of subjects such as children, prisoners, pregnant women, or handicapped or mentally disabled persons, consideration be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects;
- make every nondiscriminatory effort to ensure that the IRB does not consist entirely of men or entirely of women;
- not consist entirely of members of one profession; and
- include at least one member whose primary concerns are in scientific areas (e.g., MD, DO, DDS, Ph.D, PharmD or Bachelor of Science in Nursing, one member whose primary concerns are in non-scientific areas, and one individual who is not affiliated with the institution, nor is an immediate member of the family of a person affiliated with the institution. (For the

purpose of this policy, affiliation means employment by Marshfield Clinic, and immediate means spouse, sibling, or parent or child).

- In addition, MCRF IRB will have at least one member who represents the perspective of research participants through personal experience in that role.

b. The regulations also indicate that an IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.

### 3.2. Appointment and Composition

#### a. New MCRF IRB Members

- The IRB Chairperson and IRB Administrator in the Office of Research Integrity & Protections (ORIP) will recruit new MCRF IRB members as needed to meet the stated regulations. Prospective new members will be discussed with the Executive Director and/or Associate Director of MCRF. An IRB appointment letter will come from one of them.
- Efforts will be made to recruit a variety of individuals to serve as MCRF IRB members whose primary concerns are non-scientific, such as clergy, attorneys, educators, or businesspersons. In order to serve as an IRB member, an individual must be willing to complete human subjects protection training, IRB member orientation, attend at least 70% of IRB meetings, and be willing to serve as a primary reviewer for any and all business that comes before the IRB.
- Individuals who are directly responsible for business development or financial management of MCRF will not be appointed to serve on the IRB. Nor will they be allowed to carry out day-to-day operations of the review process.

#### b. MCRF IRB Chairperson

- The IRB Chairperson will be appointed by the Chairperson of the Board of Trustees and the Executive Director of MCRF. The Chairperson will have an educational and experiential background in a scientific field and be capable of managing the IRB and the matters brought before it with fairness and impartiality. A minimum of three years of experience as an IRB member is desirable but not required.
- The Chairperson may appoint a Vice-Chairperson from the membership of the Board, at his/her discretion. The Vice-Chair's primary responsibility is to conduct meetings in the Chair's absence.

#### c. Consultants

- When individuals with necessary expertise are not available to conduct a knowledgeable review of a specific study, the IRB will utilize IRB consultants to supplement the review process. Consultants are not allowed to vote.

### 3.3. Term Limits

- a. The federal regulations do not speak to the length of terms for IRB members, or whether there should be term limits, but MCRF Administration believes that terms should be long enough to allow MCRF IRB members to fully understand and apply human subject protection requirements, while not becoming so long that they deter individuals from serving on the IRB. MCRF Administration also believes that term limits are useful in ensuring that there is adequate rotation on MCRF IRB, which is helpful in maintaining a proper balance among experienced and novice members and ensuring that as many individuals as possible are exposed to, and support, human subject protection measures.
- b. Appointments will be for a 3-year term, with the expectation of attendance at 70% of the meetings, unless alternative arrangements have been agreed upon by the individual MCRF IRB member and the IRB Administrator of ORIP.
- c. No MCRF IRB member may serve more than two consecutive, 3-year terms, without a break before the third term, fifth term, etc. The exceptions are the IRB Chairperson, Vice-Chairperson, and IRB Administrator of ORIP.
- d. Any MCRF IRB member may have an alternate serve in the member's place, but alternates must be appointed in the same manner as other IRB members. The member and the alternate may attend the same IRB meeting, but only one may vote.
- e. If an individual is appointed to complete the term of a resigning member, this term will not be considered a full term, and therefore, the individual is eligible to serve two consecutive three-year terms after completing the term of the resigning member.

### 3.4. Compensation

- a. The IRB Chairperson is a paid position.
- b. The Salary Committee of Marshfield Clinic sets a minimal amount of compensation in the form of Relative Value Units (RVU) for Marshfield Clinic clinicians who serve as members. This compensation is intended to help offset lost patient-seeing time. There is no compensation for other members.

### 3.5. Orientation

- a. Prior to attendance as a voting member, new MCRF IRB members will receive orientation from the IRB Administrator of ORIP, the IRB Chairperson, or designee. The orientation will cover federal regulations, MCRF IRB policies and practices, and other applicable guidance. Member responsibilities will be reviewed, and members will be asked to agree to accept these responsibilities by signing an IRB member responsibility form. MCRF IRB members are also required to complete human subject protection training prior to counting toward a quorum or participating in any IRB vote.

### 3.6. Membership Roster

- a. A list of IRB members, as required and detailed in federal regulations, will be maintained and submitted as required by the federal regulations. This roster will be updated by ORIP staff to reflect changes in membership.

#### 4. ADDITIONAL RESOURCES

- 4.1. References:  
• None
- 4.2. Supporting documents available:  
• None

#### 5. DOCUMENT HISTORY

Version No.	Revision Description
1.0	New Document in Document Control system transferred from Policy & Handbook Library - #695.10. Also updated professional titles of personnel within ORIP mentioned within policy.
2.0	Revised sect. 3.2.b IRB Chair requirements
3.0	

#### 6. DOCUMENT PROPERTIES

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