



## IRB Chair, IRB Member and IRB Staff Evaluation Process

### 1. SCOPE

- 1.1. IRB Chair, IRB members and IRB staff

### 2. DEFINITIONS & EXPLANATIONS OF TERMS

- 2.1. None

### 3. PROCEDURE BODY

The periodic evaluation of the IRB Chair and IRB members is essential to a well-functioning human research protection program and IRB. Evaluations serve to validate performance, identify areas which need improvement, and allow for changes when appropriate.

#### 3.1. IRB Chair Evaluation

- a. On an annual basis, the Research Compliance Officer (RCO) will initiate a request to the IRB Chair to complete a self-evaluation instrument. At the same time, the RCO will ask all IRB members, IRB staff and investigators to complete an IRB Chair evaluation instrument.
- b. Evaluation instruments will include both objective and subjective measures of performance which may include, but are not limited to:
  - Number of meetings chaired
  - Number of protocols reviewed via expedited or staff review
  - Number of reviews (new protocol, amendment, CR, etc.) completed as a primary reviewer
  - Completion of required education in a timely manner
  - Attendance at non-required IRB-related educational events
  - Number of education sessions conducted
  - Timeliness of expedited review process
  - Timeliness of convened board review process
  - Knowledge of applicable regulations
  - Knowledge of applicable organizational policies
  - Completion of required checklists
  - Leadership of the IRB
  - Annually reviewing and signing the IRB Member COI policy and recusing oneself from review and vote when conflicted
  - Preparedness for meetings
  - Communication with investigators

- Communication with organizational officials
  - Communications and ability to work with IRB staff
  - Ability to assist investigators
- c. A summary of the completed evaluation instruments will be prepared by the RCO, and those results, along with the IRB Chair's self-evaluation instrument, will be presented to MCRF's Executive Director and Associate Director.
- d. The Executive Director or Associate Director will meet with the IRB Chair to review the results, recognize the IRB Chair's contributions and strengths, and make arrangements to assist the Chair in any identified areas of needed improvement.

### 3.2. Evaluation of IRB Members

- a. On an annual basis, the RCO will initiate a request to IRB members to complete a self-evaluation instrument. The instrument will provide members the opportunity to consider their performance and expertise as an IRB member and to identify any areas for improvement. The evaluation instrument will include areas of responsibility discussed at IRB member orientation including:
- Attendance
    - Percent of meetings attended
    - Promptness in arriving at meeting and commitment to stay through entire meeting, wherever possible
    - Notification of ORIP staff in sufficient time to accommodate scheduling of reviewers when unable to attend
  - Knowledge of federal regulations and institutional policies and procedures
    - Participation in orientation and timely completion of required CITI training
    - Understanding and application of ethical principles
    - Familiarity and application of criteria for IRB approval
    - Use of reviewer checklist
    - Attendance at optional training opportunities
  - Meeting Preparation and Review of Protocols
    - Conducting systematic evaluation of assigned items using reviewer checklists
    - Participation in meetings including contributions as the presenting primary reviewer, contributing primary reviewer
    - Familiarity with all items on the agenda
  - Maintaining confidentiality
  - Conflict of Interest (COI) Disclosure
    - Annually reviewing and signing the IRB Member COI policy
    - Recusing oneself from review and vote when conflicted

- Subcommittee Service
  - Serving on IRB subcommittees when requested and able
  - Contributing toward subcommittee products (e.g., forms, guidance documents)

b. The completed self-evaluation instruments will be submitted to the IRB Chair who will provide written feedback to each member. The Chair or member may also request a face-to-face meeting to review the results of the self-evaluation. The Chair's feedback will provide the Chair the opportunity to recognize the IRB member's contributions and strengths, and make arrangements to assist the member in any identified areas of needed improvement.

### 3.3. Evaluation of IRB Staff

IRB staff will be evaluated consistent with Marshfield Clinic's performance management evaluation requirements. Included in this review will be consideration of the staff member's:

- a. Efficiency in handling workload
- b. Timeliness of processing materials
- c. Completion of required checklists
- d. Maintenance of records
- e. Timeliness of agendas and minutes
- f. Knowledge of applicable regulations
- g. Knowledge of applicable organizational policies
- h. Timeliness of required education
- i. Attendance at and contributions to non-required educational sessions
- j. Preparedness for meetings
- k. Communication with IRB Chair, IRB members, investigators, supervisor and other IRB staff

## 4. ADDITIONAL RESOURCES

- 4.1. References:
  - None
- 4.2. Supporting documents available:
  - IRB Chair Self Evaluation Instrument
  - IRB Chair Evaluation Instrument

**5. DOCUMENT HISTORY**

Version No.	Revision Description
1.0	New Document in Document Control transferred from Policy & Handbook Library - #5281.0 Changed Director of ORIP function to Research Compliance Officer (RCO). Change 3.1(a) Change involvement of a "random group of members" to "all members" provide input to IRB Chair evaluation.
2.0	Remove section 3.4 regarding Consideration of membership composition as it is duplicative of IRB Membership resource guide.
3.0	

**6. DOCUMENT PROPERTIES**

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