

<b>James Madison University</b> <b>Office of Research Integrity and Institutional Review Board</b> <b>Standard Operating Procedures</b>			
<b>TITLE: Membership of IRB</b>			
<b>SOP # 11</b>	<b>Revision # 0</b>	<b>Effective Date: 10/3/16</b>	<b>Page 1 of 5</b>

## **OBJECTIVE**

To define policies and procedures for appointing Institutional Review Board (IRB) members.

## **GENERAL DESCRIPTION**

The IRB will consist of a minimum of eleven members representative of a variety of professional disciplines, including at least one member of the student body and one person who is not affiliated with the university, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The membership will be drawn in compliance within the diversity, competency and professional guidelines established by [45 CFR 46.107](#) of the Federal Regulations and [JMU Policy # 1104](#). The members will be appointed annually by the President upon recommendation by the Department Head, IRB chair, and the Office of Research Integrity (ORI).

In addition, the IRB includes members who can determine the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. If the IRB regularly reviews research involving a vulnerable category of subjects, the IRB membership includes individuals who are knowledgeable about and experienced in working with those subjects.

Furthermore, the IRB invites 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.

## **RESPONSIBILITY**

Execution of SOP: ORI, IRB, and IRB Chair

## **PROCEDURES**

### *Appointment Procedures/Terms of Membership*

1. The President appoints members to standing University research committees and appoints the Chair and members to the IRB. Approximately once a year upon request, the ORI submits recommendations for membership to the Office of the President. The ORI is responsible for soliciting recommendations from a variety of sources for either non-tenure track faculty/staff or individuals (preferably) in a tenured position, preparing the recommendations for submission to the Office of the President, and ensuring that the membership meets federal requirements. Other James Madison University (JMU) administrative units may also submit nominations for membership on the IRB.

<b>James Madison University</b> <b>Office of Research Integrity and Institutional Review Board</b> <b>Standard Operating Procedures</b>		
<b>SOP # 11</b>	<b>TITLE: Membership of IRB</b>	<b>Page: 2 of 5</b>
<b>Revision #0</b>		

2. The ORI provides the IRB Chair with a copy of the recommendations sent to the Office of the President.
3. Appointments for the IRB Chair and IRB members (including alternates) are for staggered three-year terms beginning the fall of each academic year. JMU has no limit on the number of terms the IRB Chair, members, and alternates may serve on the IRB.
4. The Office of the President automatically reappoints the *ex officio* member each year.
5. Individuals under consideration for appointment as an IRB Chair must meet the following requirements: completion of human research protections training; display of adequate knowledge of ethical principles, professional standards, federal regulations, and other applicable law, through IRB meeting attendance and participation; and demonstration of professional competence necessary to review specific research activities.
6. Individuals under consideration for appointment as voting IRB members must not have competing business interests or hold research business positions at JMU. In addition, individuals who are responsible for business development do not carry out day-to-day operations of the review process.
7. Alternate IRB members replace regular IRB members who are unable to attend convened meetings of the IRB. Alternate members have qualifications comparable to the applicable regular member and may be alternates for more than one IRB member. The ORI designee maintains lists of alternate members on the official membership list approved by OHRP. Terms of appointment, length of service, and duties are identical to those for regular IRB members.
8. Alternates attending a meeting or conducting a protocol review have all the authority of regular IRB members and receive the same training and protocol review application materials as the regular members. If the regular member and his/her alternate attend the same convened meeting, only one individual may vote.
9. *Ex officio* member is a non-voting member who serves as who is able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.
10. When the IRB reviews research that involves prisoners, a majority of the IRB (exclusive of the prisoner representative) must have no association with the prison involved, apart from their relationship on the IRB.

<b>James Madison University</b>		
<b>Office of Research Integrity and Institutional Review Board</b>		
<b>Standard Operating Procedures</b>		
<b>SOP # 11</b>	<b>TITLE: Membership of IRB</b>	<b>Page: 3 of 5</b>
<b>Revision #0</b>		

- For IRB review of research on prisoners, at least one voting member at the IRB meeting must be a prisoner or a prisoner representative with appropriate background and experience to serve in that capacity.

#### *Filling Appointments Due to Resignations During the Year*

- The ORI solicits recommendations from a variety of sources and makes recommendations for replacement of members who resign during the year. ORI staff sends a copy of the recommendations to the IRB Chair. The Office of the President makes all final appointments.

#### *OHRP IRB Registration/IRB Membership Roster*

- The ORI Director or his/her designee completes the OHRP IRB registration forms in accordance with OHRP registration requirements and updates the registration in a timely manner when the IRB membership changes. The OHRP registration form serves as the IRB roster and denotes in which scientific capacity each member serves.
- The ORI maintains membership records. ORI staff use the OHRP membership list as the official membership list to determine who may attend IRB meetings and count toward the quorum. It includes a list of regular members and their designated alternates and indicates the scientific status of all members.
- To meet OHRP registration requirements and in order to hold convened meetings, the scientist and nonscientist member designations are as follows:
  - Nonscientific: members who have had little or no scientific or medical training or who do not currently hold positions which involve scientific research or clinical practice (e.g., administrative positions).
  - Scientific: members who are physicians or who hold Ph.D., Pharm.D., or other advanced degrees who are actively engaged in research in the physical, educational, social, behavioral, or biological sciences and disciplines and/or hold regular faculty appointments.

#### *Membership Requirements*

- Training: Upon appointment to the IRB, members will be complete the “IRB Member” course through the Collaborative Institutional Training Initiative (CITI) Program. Training must be renewed every three years.
- Evaluation forms: Evaluation forms of Expedited reviews are due within (5) business days of assignment. Full Board evaluations are due the Monday before the convened meeting at 12:00 p.m. Signed evaluation forms are also to be submitted to ORI. A committee member who is unable to review an assigned protocol is to notify the IRB

<b>James Madison University</b> <b>Office of Research Integrity and Institutional Review Board</b> <b>Standard Operating Procedures</b>		
<b>SOP # 11</b> <b>Revision #0</b>	<b>TITLE: Membership of IRB</b>	<b>Page: 4 of 5</b>

staff immediately. If an evaluation form is not received by the due date, the assigned reviewer will receive (1) courtesy reminder before a protocol is reassigned to another committee member. A committee member who has had an individual review reassigned (3) times without prior communication with the IRB staff of their unavailability may be removed from committee.

- Attendance: Attendance at all convened meetings unless the IRB support staff is notified of any conflicts.

*Removal for Cause of a Member*

- Justification for Removal: To remove a member of an IRB, including the Chair or Vice Chair, before the end of that person’s appointed term, just cause must be shown of that person’s inability to meet his/her responsibilities, such as failure to attend meetings regularly; failure to submit evaluation forms on time (five business days for Expedited reviews and 8:00 a.m. on Monday before convened meeting for Full Board reviews); failure to follow applicable laws, regulations and policies; mismanagement; inappropriate tone in written or verbal comments to researchers; negative body language during convened meetings; misconduct, or an unresolved conflict of interest for which recusal is insufficient.
- Procedures for Removal: The Director of ORI, after consultation with the IRB Chair (if the Chair is not the member in question) shall prepare a written memorandum to the President’s Office with the reasons for recommending termination of membership. The President’s Office makes the final decision on termination and sends a termination letter to the member if the President concurs with the recommendation for the member’s removal from the IRB.
- Termination letters are copied to the IRB Chair and the IRB administrative office.

**REVISION HISTORY**

<b>Version No.</b>	<b>Brief Description of Changes</b>	<b>Created on Date</b>
00	Creation of SOP	7/20/2015

**SIGNATURE HISTORY**

<b>Name and Title</b>	<b>Signature</b>	<b>Date</b>
-----------------------	------------------	-------------

**James Madison University  
Office of Research Integrity and Institutional Review Board  
Standard Operating Procedures**

**SOP # 11  
Revision #0**

**TITLE: Membership of IRB**

**Page: 5 of 5**


**REFERENCES**

- [45 CFR 46.103\(b\)\(3\)](#)
- [45 CFR 46.115\(a\)\(5\)](#)
- [45 CFR 46.107](#)
- [45 CFR 46 Subpart E](#)
- [JMU Policy 1104](#)