

UNIVERSITY OF SOUTHERN MAINE  
Office of Research Integrity & Outreach

<b>Procedure #:</b>	HRPP-033
<b>AAHRPP:</b>	Element II.1.B.
<b>Date Adopted:</b>	4/28/2020
<b>Last Updated:</b>	4/16/2020
<b>Prepared By:</b>	Casey Webster, Research Compliance Administrator
<b>Reviewed By:</b>	IRB Chair; IRB; ORIO
<b>Procedure Title:</b>	IRB Member Evaluation

### **1.0 Objective**

- 1.1. To describe the policies and procedures for the periodic assessment of Institutional Review Board (IRB) members, Chairs, Vice Chair s, and Office of Research Integrity and Outreach (ORIO) staff performing IRB related functions.

### **2.0 General Description**

- 2.1. Evaluations serve to validate performance, identify areas that need improvement, and make changes when appropriate.
- 2.2. Evaluations are performed periodically, usually scheduled to occur at the time of a member's re-appointment.
- 2.3. Where ORIO staff also serve as IRB members, they are evaluated by both staff and member procedures.
- 2.4. Where the Research Compliance Administrator (RCA), is ORIO staff, the RCA may designate an IRB Chair, Vice Chair, member, or ORIO staff to complete evaluation procedures for the RCA.

### **3.0 Responsibility**

- 3.1. It is the responsibility of ORIO staff, the Research Compliance Administrator (RCA), and the IRB to execute this Standard Operating Procedure (SOP).

### **4.0 Procedure**

- 4.1. IRB Chair and Vice Chair Evaluation
  - 4.1.1. On a regular basis, (annually or at the time of re-appointment), the RCA or designee will initiate a request to the IRB Chair(s) and Vice Chair(s) to complete a self-evaluation instrument.

4.1.1.1. At the same time, the RCA will ask all IRB members and select ORIO staff to complete a Chair and Vice Chair evaluation instrument.

**4.1.2.** Evaluation instruments will include both objective and subjective measures of performance. (*See IRB Chair and Vice Chair Evaluation.docx*)

**4.1.3.** A summary of the completed evaluation instruments will be prepared by the RCA or designee, and those results will be presented to the Chair and Vice Chair.

4.1.3.1. The RCA or designee will meet with the Chair and Vice Chair to review the results, recognize the Chair or Vice Chair's contributions and strengths, and make arrangements to assist the Chair or Vice Chair in any identified areas of needed improvement.

## **4.2. IRB Member Evaluation**

**4.2.1.** On a regular basis (annually or at the time of re-appointment), the RCA or designee will initiate a request to individual IRB members to complete a self-evaluation instrument.

4.2.1.1. At the same time, the RCA will ask the IRB Chair, Vice Chair, and select ORIO staff to complete an evaluation instrument for the individual IRB member.

**4.2.2.** Evaluation instruments will include the areas of responsibility listed in IRB member appointment letters and discussed at new member meetings. (*See IRB Board Member Evaluation.docx*)

**4.2.3.** A summary of the completed evaluation instruments will be prepared by the RCA or designee, and those results will be presented to the IRB member.

4.2.3.1. The RCA or designee, Chair, and Vice Chair will meet with the IRB member to review the results, recognize the member's contributions and strengths, and make arrangements to assist the member in any identified areas of needed improvement.

## **4.3. ORIO Staff Evaluation**

**4.3.1.** On a regular basis, (annually or at a designated time of year) the RCA or designee will initiate a request to an individual ORIO staff person to complete a self-evaluation instrument.

4.3.1.1. At the same time, the RCA will ask all other ORIO staff to complete an evaluation instrument for the individual ORIO staff person.

- 4.3.2. Evaluation instruments will include areas of IRB administrative responsibility. (See *IRB Staff Member Evaluation.docx*).
- 4.3.3. A summary of the completed evaluation instruments will be prepared by the RCA or designee, and those results will be presented to the ORIO staff person.
  - 4.3.3.1. The RCA or designee will meet with the ORIO staff person to review the results, recognize the member's contributions and strengths, and make arrangements to assist the member in any identified areas of needed improvement.

## **5.0 References**

- 5.1. 45 CFR 46.107;
- 5.2. 45 CFR 46.304;
- 5.3. OHRP Guidance on Written Institutional Review Board (IRB) Procedures;
- 5.4. 21 CFR 56.107;
- 5.5. FDA Information Sheets: Non-Local IRB Review;
- 5.6. IRB Membership;
- 5.7. AAHRPP Tip Sheet 7: Evaluation of IRB Chairs, Vice Chair s, IRB Members, and IRB Staff.