

# Standard Operating Procedure (SOP)

<b>SOP #: 401.132</b>	<b>HRP-132 IRB Member Addition</b>
<b>Executive Owner: Vice President Research Operations</b>	<b>Effective Date: 7/15/2015</b>
	<b>Review Date: 09/09/2020</b>

<b>Scope</b>	This SOP applies to the [HRPP Administrator].
<b>Purpose</b>	This procedure establishes the process to add an IRB member to an IRB. This procedure begins when the [Organizational Official] selects a new IRB member. This procedure ends when the individual is not offered IRB membership, or the member has been added and the IRB's registration has been updated.
<b>Qualified Personnel</b>	The [HRPP Administrator] carries out these procedures.
<b>Training</b>	Not applicable.
<b>Supplies &amp; Equipment</b>	Not applicable.
<b>Procedure</b>	<ol style="list-style-type: none"> <li>1. IRB members will be selected based on qualifications, education, experience, and having a positive attitude toward board membership.</li> <li>2. The [IRB Executive Chair] should normally be an IRB member who is a respected individual with knowledge of research ethics, regulations, guidance, and HRPP policies and procedures.</li> <li>3. IRB chairs and vice-chairs:             <ol style="list-style-type: none"> <li>3.1. Discharge the [IRB Executive Chair]'s responsibilities when the [IRB Executive Chair] is unable to do so</li> <li>3.2. Discharge the responsibilities assigned by the [IRB Executive Chair]</li> <li>3.3. Assist in the operation of the IRB</li> </ol> </li> <li>4. Begin IRB New Member Orientation Checklist</li> <li>5. Request the individual to complete the IRB Application and New Member Information Sheet</li> <li>6. Obtain a copy of the individual's résumé or curriculum vitae.</li> <li>7. Provide the résumé or curriculum vitae to the [Organizational Official] for review and approval.</li> <li>8. If the [Organizational Official] agrees that the background of the potential member is a good fit with the current membership of the IRB, telephone or in-person interviews will be conducted with an appropriate selection of IRB chairs, members, and others as determined necessary. The potential IRB member may also attend and observe an IRB meeting.</li> <li>9. At the completion of the appropriate interviews, the designee will notify the [Organizational Official] that the interviews have been conducted and will summarize the opinions of the interviewers, and make a recommendation with regard to having the potential IRB member begin IRB member training.</li> </ol>

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10. Upon successful completion or verification of training, the IRB Chair notifies the [Organizational Official] that the individual has completed training and assesses whether they have completed the training in a satisfactory manner to be appointed as a board member.
11. If the training has been satisfactory and the [Organizational Official] agrees, appoint the IRB member, and update the IRB roster. If the training has not been satisfactory, The IRB Chair and [Organizational Official] will either agree on a plan for additional training or will decline to offer IRB membership to the potential IRB member.
12. Prepare an appointment letter, have it signed by the [Executive IRB Chair], and send to the individual.
13. Have the individual sign the IRB member agreement.
14. Obtain information from the individual to complete the roster.
15. Use “WORKSHEET: IRB Composition (HRP-430)” to evaluate whether the IRB is appropriately constituted.
16. Revise the membership as needed.
  - 16.1. If the new member is a chair, update the IRB’s registration at <http://ohrp.cit.nih.gov/efile/> within 90 days.

**Definition(s)**

**IRB:** Institutional Review Board

**Reference(s)**

21 CFR §56.106 and §56.107  
45 CFR §46.107 and 45 CFR §46 Subpart E

**Related Documents**

WORKSHEET: IRB Composition (HRP-430)  
IRB New Member Orientation Checklist

**Keywords**

IRB, institutional review board, IRB member