



SOP: IRB Member Addition

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1. PURPOSE

- 1.1. This procedure establishes the process to add an IRB member to an IRB.
- 1.2. This procedure begins when a potential IRB member has been identified.
- 1.3. 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.

2. POLICY

- 2.1. IRB members will be selected based on qualifications, education, experience, and having a positive attitude toward board membership.
- 2.2. The IRB Chair should normally be an IRB member who is a respected individual with knowledge of research ethics, regulations, guidance, and HRPP policies and procedures.
- 2.3. IRB chairs and vice-chairs:
 - 2.3.1. Discharge the IRB Chair's responsibilities when the IRB Chair is unable to do so.
 - 2.3.2. Discharge the responsibilities assigned by the IRB Chair.
 - 2.3.3. Assist in the operation of the IRB.

3. RESPONSIBILITY

- 3.1. The HRPP Administrator carries out these procedures.

4. PROCEDURE

- 4.1. Obtain a copy of the individual's résumé or curriculum vitae.
- 4.2. Provide the résumé or curriculum vitae to the Institutional Official for review.
- 4.3. If the Institutional 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 at least one Institutional Official member. The potential IRB member may also attend and observe an IRB meeting.
- 4.4. At the completion of the appropriate interviews, the designee will notify the Institutional 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.
- 4.5. Upon successful completion or verification of training, the IRB Chair notifies the Institutional Official that the individual has completed training and assesses whether they have completing the training in a satisfactory manner to be appointed as a board member.
- 4.6. If the training has been satisfactory and the Institutional Official agrees, appoint the IRB member, and update the IRB roster. If the training has not been satisfactory, the IRB Chair and Institutional Official will either agree on a plan for additional training, or will decline to offer IRB membership to the potential IRB member.
- 4.7. Prepare an appointment letter, have it signed by the IRB Chair, and send to the individual.
- 4.8. Have the individual sign the IRB confidentiality agreement.
- 4.9. Obtain information from the individual to complete the roster.
- 4.10. Use "WORKSHEET: IRB Composition (HRP-430)" to evaluate whether the IRB is appropriately constituted.
- 4.11. Revise the membership as needed.
- 4.12. If the new member is a chair, update the IRB's registration at <http://ohrp.cit.nih.gov/efile/> within 90 days.

5. REFERENCES

- 5.1. 21 CFR §56.106 and §56.107
- 5.2. 45 CFR §46.107 and 45 CFR §46 Subpart E