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1. PURPOSE

- 1.1. This procedure establishes the process to add a Regular or Alternate 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 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.
- 2.3. IRB chairs and vice-chairs:
 - 2.3.1. Discharge the [IRB Executive Chair]'s responsibilities when the [IRB Executive Chair] is unable to do so.
 - 2.3.2. Discharge the responsibilities assigned by the [IRB Executive 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 [Organizational Official] for review.
- 4.3. 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 at least one [Organizational 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 [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.
- 4.5. 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 completing the training in a satisfactory manner to be appointed as a board member.
- 4.6. 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.
- 4.7. Prepare an appointment letter, have it signed by the [Executive IRB Chair], and send to the individual.
- 4.8. Have the individual sign the IRB member 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.

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5. REFERENCES

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