

**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 the [Organizational Official] selects a new IRB member.
- 1.3. This procedure ends when the member has been added and the IRB's registration has been updated.

**2. POLICY**

- 2.1. 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.
- 2.2. IRB chairs and vice-chairs:
  - 2.2.1. Discharge the [IRB Executive Chair]'s responsibilities when the [IRB Executive Chair] is unable to do so
  - 2.2.2. Discharge the responsibilities assigned by the [IRB Executive Chair]
  - 2.2.3. Assist in the operation of the IRB

**3. RESPONSIBILITY**

- 3.1. The [HRPP Administrator] carries out these procedures.

**4. PROCEDURE**

- 4.1. Determine whether the individual will be a regular IRB member, alternate IRB member, IRB chair, or IRB vice-chair.
- 4.2. Obtain a copy of the individual's résumé or curriculum vitae.
- 4.3. Provide the résumé or curriculum vitae to the [Organizational Official] for review and approval.
- 4.4. If not approved by the [Organizational Official] stop processing.
- 4.5. If the individual requires training, have the individual undergo training.
- 4.6. Upon successful completion or verification of training, appoint the IRB member, and update the IRB roster.
- 4.7. Obtain information from the individual to complete the roster.
- 4.8. Prepare an appointment letter, have it signed by the [Organizational Official], and send to the individual.
- 4.9. Have the individual sign the IRB member agreement.
- 4.10. Evaluate whether the IRB is appropriately constituted according to federal, state, and local laws.
  - 4.10.1. Revise the membership as needed.
- 4.11. 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