

## SOP: IRB Membership Appointment

### 1 PURPOSE

- 1.1 This procedure establishes the process to appoint and re-appoint an IRB member.
- 1.2 The process begins when an individual expresses interest, is nominated or applies to join the IRB in consultation with the Institutional Official/ Organizational Official (IO/OO) (this may be a completely new IRB member, or re-appointment of a previous member).
- 1.3 The process ends when the IRB roster is updated and the new member has completed training.

### 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

### 3 POLICY

- 3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.
- 3.2 IRB members /alternates are appointed for a three-year term. Members/alternates are eligible for re-appointment at the end of their term.
- 3.3 The following individuals may not be appointed as IRB members or be involved in the day-to-day operations of the IRB:
  - 3.3.1 Those responsible for business development for the organization (e.g., director of grants and contracting, the vice president for research, deans of research who are responsible for raising funds or garnering support for research, senior officers).
  - 3.3.2 Those who own equity in the organization.

### 4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.
- 4.2 The IO/OO or designee appoints/re-appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs.).

### 5 PROCEDURE

- 5.1 Have the individual complete HRP-202 - FORM - IRB Member Information.
- 5.2 Obtain a copy of the individual's résumé or curriculum vita.
- 5.3 Use the information in the completed HRP-202 - FORM - IRB Member Information and the individual's résumé or curriculum vita to determine if the individual qualifies as a scientist or nonscientist, and if they are affiliated or unaffiliated<sup>i</sup>.
- 5.4 Interview the individual to assess suitability and availability.
  - 5.4.1 Determine from the IO/OO or designee whether the individual will be a regular IRB member, alternate IRB member, or IRB chair.
  - 5.4.2 In any instance for which the scientific or non-scientific status or affiliation status of a newly appointed or re-appointed IRB member may be questionable, the IO/OO or designee will be consulted before proceeding with the appointment.
- 5.5 Schedule a time for the applicant to attend and observe an IRB meeting, as applicable.
- 5.6 Add the individual to HRP-601 - DATABASE - IRB Roster.

- 5.7 Complete HRP-304 - WORKSHEET - IRB Composition and revise the membership as needed to ensure that the IRB is appropriately constituted.
- 5.8 Prepare HRP-560 - LETTER - IRB Member Appointment for the individual.
- 5.9 Provide to the IO/OO or designee for review and approval:
  - 5.9.1 HRP-202 - FORM - IRB Member Information.
  - 5.9.2 Résumé or curriculum vita.
  - 5.9.3 Completed HRP-560 - LETTER - IRB Member Appointment.
- 5.10 If not approved, select another individual and restart at 5.1.
- 5.11 Once the appointment letter is signed:
  - 5.11.1 Send the signed HRP-560 - LETTER - IRB Member Appointment to the individual.
  - 5.11.2 If the individual requires training, schedule the individual for training.
  - 5.11.3 Update the registration of all affected IRBs.<sup>ii</sup>
- 5.12 File:
  - 5.12.1 HRP-601 - DATABASE - IRB Roster.
  - 5.12.2 Signed IRB appointment/re-appointment letter.
  - 5.12.3 HRP-202 - FORM - IRB Member Information.
  - 5.12.4 Résumé or curriculum vita.
  - 5.12.5 Any other signed agreements.
- 5.13 Notify the IRB manager when the individual has completed training.

## 6 MATERIALS

- 6.1 HRP-202 - FORM - IRB Member Information
- 6.2 HRP-304 - WORKSHEET - IRB Composition
- 6.3 HRP-560 - LETTER - IRB Member Appointment
- 6.4 HRP-601 - DATABASE - IRB Roster

## 7 REFERENCES

- 7.1 45 CFR §46.107, 45 CFR §46.108(a)(2), 45 CFR §46.115(a)(5).
- 7.2 21 CFR §56.107, 21 CFR §56.115(a)(5).
- 7.3 AAHRPP elements I.1.E, II.1.A-C

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<sup>i</sup> See [OHRP's IRB Registration Process FAQ](#) "How do I determine the various categories of members for the IRB roster?" and [FDA's IRB FAQs on IRB Membership](#) for additional guidance.

<sup>ii</sup> See <http://www.hhs.gov/ohrp/assurances/>. Use Web site: <http://ohrp.cit.nih.gov/efile/>.