



SOP: IRB Membership Appointment				
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## 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 the HRP-601 - DATABASE - IRB Roster.
- 3.2 IRB members /alternates are appointed for a five-year term. Members/alternates may be considered for re-appointment at the end of their term.

## 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.
- 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.
  - 5.4.3 Send new member IRB Confidentiality Agreement for review and signature
- 5.5 Schedule new member to observe one IRB meeting before approval as an IRB Member
- 5.6 Provide to the IO/OO or designee for review and approval:
  - 5.6.1 Attach the HRP-202 - FORM - IRB Member Information.
  - 5.6.2 Attach the Résumé or curriculum vita.
  - 5.6.3 Completed HRP-560 - LETTER - IRB Appointment. For IO/OO or designee signature
- 5.7 Once the appointment letter is signed:
  - 5.7.1 Add the individual to the HRP-601 - DATABASE - IRB Roster.
    - 5.7.1.1 Add updated Roster to the eIRB2 Library
  - 5.7.2 Complete HRP-304 - WORKSHEET - IRB Composition and revise the membership as needed to ensure that the IRB is appropriately constituted.
  - 5.7.3 Prepare HRP-560 - LETTER - IRB Appointment for the individual.
  - 5.7.4 Send the signed HRP-560 - LETTER - IRB Appointment to the in.
  - 5.7.5 If the individual requires training, schedule the individual for training.
  - 5.7.6 The new member would usually observe two additional meetings before being assigned their first review.
- 5.8 If not approved, select another individual and restart at 5.1.

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- 5.9 File:
  - 5.9.1 HRP-601 - DATABASE - IRB Roster
  - 5.9.2 Signed IRB appointment/re-appointment letter
  - 5.9.3 HRP-202 - FORM - IRB Member Information.
  - 5.9.4 Résumé or curriculum vita.
  - 5.9.5 Any other signed agreements
- 5.10 Notify the HRPP Director when the individual has completed training.
  - 5.10.1 Assign individual the “Committee Member” role in the system.
  - 5.10.2 If the individual is designated to conduct non-committee reviews, update the “Update Eligible Designated Reviewers” activity.

## 6 MATERIALS

- 6.1 HRP-202 - FORM - IRB Member Information
- 6.2 HRP-304 - WORKSHEET - IRB Composition
- 6.3 HRP-560 - LETTER - IRB Appointment
- 6.4 HRP-561 - LETTER - IRB Thank You
- 6.5 HRP-601 – DATABASE – IRB Roster
- 6.6 IRB Confidentiality Agreement

## 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