	SOP: IRB Membership Appointment		
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1 PURPOSE

- 1.1 This SOP establishes the process to appoint or 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 or designee. (This may be a completely new IRB member, or reappointment of a previous member to another IRB.)
- 1.3 The process ends when the IRB registration is updated with OHRP and the new member has completed New IRB Member Orientation.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Revised from the 5/30/2017 version.

3 SOP Statement


- 3.1 IRB rosters are maintained using the IRB Roster Sheet.
- 3.2 IRB members/alternates are appointed for a three-year term or less if the appointment starts in the middle of a fiscal year. Members/alternates are eligible for re-appointment at the end of their term.

4 RESPONSIBILITIES

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

5 PROCEDURE

- 5.1 Send HRP-202 - FORM - IRB Member Information to the individual.
- 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 Institutional Official 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/QO or designee will be consulted before proceeding with the appointment.
- 5.5 When applicable, allow the applicant to attend and observe an IRB meeting.
- 5.6 Add the individual to the IRB Roster Sheet.
- 5.7 Use HRP-304 - WORKSHEET - IRB Composition and revise the membership as needed to ensure that the IRB is appropriately constituted.
- 5.8 Prepare an IRB Member Appointment Letter Merge Tool for the individual.
- 5.9 Provide to the Institutional Official or designee for review and approval:
 - 5.9.1 Résumé or curriculum vita.
 - 5.9.2 HRP-202 - FORM - IRB Member Information.
 - 5.9.3 IRB Member Appointment Letter Merge Tool
- 5.10 Once the appointment letter is signed by the Institutional Official or designee:
 - 5.10.1 Send the signed IRB Member Appointment Letter to the individual.
 - 5.10.2 Have the new Committee member sign the letter and return to the Institutional Official or designee.
 - 5.10.3 If the individual requires training, schedule the individual for IRB New Member Orientation.
 - 5.10.4 Update the registration of all affected IRBs at [Update or Renew an IRB Registration | HHS.gov](#) within 90 days.
- 5.11 File:
 - 5.11.1 IRB Roster Sheet

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- 5.11.2 Copy of IRB Member résumé or curriculum vita
- 5.11.3 Copy of HRP-202 - FORM - IRB Member Information
- 5.12 When the new IRB member has completed orientation:
 - 5.12.1 Assign individual the role of IRB Committee Reviewer in the electronic system.
 - 5.12.2 If the individual is designated to conduct non-committee reviews, assign the Expedited Reviewer role in the electronic system.

6 MATERIALS

- 6.1 IRB Roster Sheet
- 6.2 HRP-202 - FORM - IRB Member Information
- 6.3 HRP-304 - WORKSHEET - IRB Composition

7 REFERENCES

- 7.1 45 CFR §46.103, 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