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/OO 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

mailto:
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