



SOP: IRB Membership Appointment

NUMBER	DATE	PAGE
2.003 (HRP-082)	4/29/2024	1 of 2

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. This may be a new IRB member or a 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 7/1/20.

3 POLICY

- 3.1 IRB rosters are maintained using 2.306 (HRP-601) - DATABASE - IRB Committee Member Profile (in eIRB+).
- 3.2 IRB members /alternates are appointed for a one-year term. Members/alternates are eligible for re-appointment at the end of their term.

4 RESPONSIBILITIES

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

5 PROCEDURE

- 5.1 Have the individual complete the IRB Committee Member Profile in eIRB+.
- 5.2 Obtain a copy of the individual's résumé or curriculum vitae.
- 5.3 Use the information in the completed profile and the individual's résumé or curriculum vitae to determine if the individual qualifies as a scientist or nonscientist and affiliated or nonaffiliated.
- 5.4 Interview the individual to assess suitability and availability.
 - 5.4.1 Determine from the IO or designee whether the individual will be a regular IRB member, alternate IRB member, IRB vice chair, 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 or designee will be consulted before proceeding with the appointment.
- 5.5 Schedule a time for the applicant to attend and observe IRB meetings, as applicable.
- 5.6 Schedule the individual for orientation and CITI training.
- 5.7 After orientation and training are completed, add the individual to the IRB Roster.
- 5.8 Complete 2.201 (HRP-304) - WORKSHEET - IRB Composition and revise the membership as needed to ensure that the IRB is appropriately constituted.
- 5.9 Update the registration of all affected IRBs.
- 5.10 Prepare 2.301-2.303 (HRP-560 a-c) - LETTER - IRB Appointment or equivalent for the individual.
- 5.11 Provide the letter to the IO or designee for review, approval, and signature, including electronic.
- 5.12 If not approved, select another individual and restart at 5.1.
- 5.13 Once the appointment letter is signed:
 - 5.13.1 Send the signed appointment letter to the individual.
 - 5.13.2 Assign individual the 'Committee Member' role in the system.
 - 5.13.3 If the individual is designated to conduct non-committee reviews, e-IRB+ will automatically update the 'Eligible Designated Reviewers' List.

6 MATERIALS

- 6.1 2.201 (HRP-304) - WORKSHEET - IRB Composition.
- 6.2 2.301-2.303 (HRP-560a-c) - LETTER - IRB Appointment.
- 6.3 2.304 (HRP-561) - LETTER - IRB Thank You.



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NUMBER	DATE	PAGE
2.003 (HRP-082)	4/29/2024	2 of 2

6.4 2.306 (HRP-601) - DATABASE - IRB Committee Member Profile (in eIRB+).

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).