

SOP: IRB Membership Removal

NUMBER

DATE

PAGE

2.004 (HRP-083)

4/29/2024

1 of 1

1 PURPOSE:

- 1.1 This procedure establishes the process to remove an IRB member.
- 1.2 The process begins when an IRB member resigns or is removed from one or more IRBs. This procedure applies if an individual is a member of more than one IRB and is being removed from some but not all IRBs.
- 1.3 The process ends when the IRB registration is updated.

2 REVISIONS FROM PREVIOUS VERSION:

- 2.1 12/1/20.

3 POLICY:

- 3.1 The Institutional Official (IO) or designee may remove IRB members, alternate members, IRB chairs, and, if used, other officers (e.g., vice chairs) with consultation from the, HRPP Director, and IRB chair(s).
 - 3.1.1 Removal of members from the IRB for cause (such as breach of confidentiality, non-compliance, etc.) may not be delegated.
- 3.2 IRB rosters are maintained using 2.306 (HRP-601) - DATABASE - IRB Committee Member Profile (in eIRB+).

4 RESPONSIBILITIES:

- 4.1 HRPP staff members carry out these procedures.

5 PROCEDURE:

- 5.1 Remove individual's privileges from committee membership.
- 5.2 Edit the individual's status in 2.306 (HRP-601) – DATABASE - IRB Committee Member Profile (in eIRB+).
- 5.3 Complete 2.201 (HRP-304) - WORKSHEET - IRB Composition to ensure that the IRB is appropriately constituted.
 - 5.3.1 If not, identify one or more replacement members and follow 2.003 (HRP-082) - SOP - IRB Membership Addition.
- 5.4 Prepare 2.304 (HRP-561) - LETTER - IRB Thank You or equivalent, have it signed by the IO or designee and send to the individual.
- 5.5 Update the registration of all affected IRBs.¹
- 5.6 File:
 - 5.6.1 2.306 (HRP-601) - DATABASE - IRB Committee Member Profile (in eIRB+).
 - 5.6.2 2.304 (HRP-561) - LETTER - IRB Thank You or equivalent.
- 5.7 Direct IT to remove an individual's "Committee Member" role in the system.
 - 5.7.1 eIRB+ automatically updates the database.

6 MATERIALS:

- 6.1 2.003 (HRP-082) - SOP - IRB Membership Addition.
- 6.2 2.306 (HRP-601) - DATABASE - IRB Committee Member Profile (in eIRB+).
- 6.3 2.201 (HRP-304) - WORKSHEET - IRB Composition.
- 6.4 2.304 (HRP-561) - LETTER - IRB Thank You.

7 REFERENCES:

- 7.1 45 CFR §46.107, 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5).
- 7.2 21 CFR §56.107, 21 CFR §56.115(a)(5).

¹ See <http://www.hhs.gov/ohrp/assurances/>. Use the Web site: <http://ohrp.cit.nih.gov/efile/>.