

SOP: IRB Membership Removal				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
HRP-083	12/1/18	T. Bechert	G. Ostrander	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 None

3 POLICY

- 3.1 The <u>Institutional Official/Organizational Official (IO/OO)</u> or designee may remove IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs) with consultation from the IRB manager and IRB chair(s).
- 3.2 IRB rosters are maintained using the "DATABASE: IRB Roster (HRP-601)."

4 RESPONSIBILITIES

4.1 IRB staff members carry out these procedures.

5 PROCEDURE

- 5.1 Remove the individual from "DATABASE: IRB Roster (HRP-601)."
- 5.2 Complete "WORKSHEET: IRB Composition (HRP-304)" to ensure that the IRB is appropriately constituted.
 - 5.2.1 If not, identify one or more replacement members and follow "SOP: IRB Member Addition (HRP-082)."
- Prepare a "TEMPLATE LETTER: IRB Member Thank You (HRP-561)," have it signed by the <u>IO/OO</u> or designee, and send to the individual.
- 5.4 Update the registration of all affected IRBs.¹
- 5.5 File:
 - 5.5.1 DATABASE: IRB Roster (HRP-601)
 - 5.5.2 TEMPLATE LETTER: IRB Member Thank You (HRP-561)
- 5.6 Remove individual's "Committee Member" role in the system.
 - 5.6.1 If applicable, update the "Update Eligible Designated Reviewers" activity.

6 MATERIALS

- 6.1 DATABASE: IRB Roster (HRP-601)
- 6.2 SOP: IRB Member Addition (HRP-082)
- 6.3 TEMPLATE LETTER: IRB Member Thank You (HRP-561)
- 6.4 WORKSHEET: IRB Composition (HRP-304)

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)

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