

SOP: IRB Removal

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1 PURPOSE

- 1.1 This procedure establishes the process to remove an IRB.
- 1.2 The process begins when the Institutional Official or designee determines that an IRB is no longer needed.
- 1.3 The process ends when the IRB is unregistered with OHRP and the federalwide assurance (FWA) is updated.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 IRB rosters are maintained using the “DATABASE: IRB Roster (HRP-601)” or equivalent.

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

5 PROCEDURE

- 5.1 For internal IRBs:
 - 5.1.1 For each IRB member who will no longer serve as an IRB member prepare a “TEMPLATE LETTER: IRB Member Thank You (HRP-561)” or equivalent, have them signed by the Institutional Official or designee, and send to the former IRB members.
 - 5.1.2 Unregister the IRB member with OHRP¹.
 - 5.1.3 Remove the IRB member from the federalwide assurance (FWA)².
 - 5.1.4 Remove members from “DATABASE: IRB Roster (HRP-601)” or equivalent.
 - 5.1.5 File:
 - 5.1.5.1 DATABASE: IRB Roster (HRP-601)
 - 5.1.5.2 Federalwide assurance (FWA)
 - 5.1.5.3 TEMPLATE LETTER: IRB Member Thank You (HRP-561)
- 5.2 For external IRBs follow the requirements of the inter-institutional agreement or contract.

6 MATERIALS

- 6.1 DATABASE: IRB Roster (HRP-601)
- 6.2 TEMPLATE LETTER: IRB Member Thank You (HRP-561)

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/>.

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