

SOP: IRB Removal

1 PURPOSE

- 1.1 This procedure establishes the process to remove an IRB.
- 1.2 The process begins when the Institutional Official/ Organizational Official (IO/OO) 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 HRP-601 - DATABASE - IRB Roster.

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 HRP-561 - LETTER - IRB Member Thank You, have them signed by the IO/OO or designee and send to the former IRB members.
 - 5.1.2 Unregister the IRB with OHRP.ⁱ
 - 5.1.3 Remove the IRB from the FWA.ⁱⁱ
 - 5.1.4 Remove members from HRP-601 - DATABASE - IRB Roster.
 - 5.1.5 Remove the individual's Committee Member role in the system.
 - 5.1.6 File:
 - 5.1.6.1 DATABASE: IRB Roster (HRP-601)
 - 5.1.6.2 FWA
 - 5.1.6.3 HRP-561 - LETTER - IRB Member Thank You
- 5.2 For external IRBs follow the requirements of the inter-institutional agreement or contract.

6 MATERIALS

- 6.1 HRP-561 - LETTER - IRB Member Thank You
- 6.2 HRP-601 - DATABASE - IRB Roster

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).
- 7.3 AAHRPP elements II.1.A, II.1.C

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

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