

	SOP: IRB Removal		
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1 PURPOSE

- 1.1 This SOP establishes the process to remove an IRB.
- 1.2 The process begins when the Institutional Official or designee decides 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

3 SOP Statement

- 3.1 The Organization maintains a roster of IRB(s) on the IRB Roster Sheet.

4 RESPONSIBILITIES

- 4.1 The HRPP Director or designee carries out these procedures.

5 PROCEDURE

- 5.1 For internal IRBs:
 - 5.1.1 Notify each IRB member who will no longer serve as an IRB member. Prepare and send HRP-561 - LETTER - IRB Member Thank You or equivalent communication, signed by the Institutional Official or designee.
 - 5.1.2 Unregister the IRB with OHRP¹.
 - 5.1.3 Remove the IRB from the Federalwide assurance (FWA)².
 - 5.1.4 Remove each individual's role as an IRB Reviewer in the electronic system
 - 5.1.5 File:
 - 5.1.5.1 IRB Roster Sheet
 - 5.1.5.2 Federalwide assurance (FWA)
 - 5.1.5.3 HRP-561 - LETTER - IRB Member Thank You
- 5.2 For external IRBs follow the requirements of any reliance agreement or contract.

6 MATERIALS

- 6.1 IRB Roster Sheet
- 6.2 HRP-561 - LETTER - IRB Member Thank You

7 REFERENCES

- 7.1 45 CFR §46.103, 45 CFR §46.107, 45 CFR §46.115(a)(5).
- 7.2 21 CFR §56.107, 21 CFR §56.115(a)(5).
- 7.3 AAHRPP II.1.A, II.1.C

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

² See <http://www.hhs.gov/ohrp/assurances/>. Use the Web site: <http://ohrp.cit.nih.gov/efile/>.