

SOP: IRB Removal				
NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
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1 PURPOSE

- 1.1 This procedure establishes the process to disband an IRB.
- 1.2 The process begins when the <u>Institutional Official/ Organizational Official (IO/OO)</u> 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
- 2.2 Reconciliation to Huron HRPP Toolkit 4.5, dated 12/10/2021

3 GUIDING PRINCIPLES

3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.

4 RESPONSIBILITIES

4.1 HSRO 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 Thank You, have them signed by the <u>IO/OO</u> or designee and send to the former IRB members.
 - 5.1.2 Unregister the IRB with OHRP.¹
 - 5.1.3 Remove the IRB from the FWA.²
 - 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 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 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

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¹ See http://ohrp.cit.nih.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/.