

SOP: IRB Removal		
NUMBER	DATE	PAGE
2.002 (HRP-081)	4/17/2024	1 of 1

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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 (IO) or designee determines that an IRB is no longer needed.
- 1.3 The process ends when the IRB is unregistered with OHRP, and the federal-wide assurance (FWA) is updated.

## 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 7/1/20.

## 3 POLICY

- 3.1 IRB rosters are maintained using 2.306 (HRP-601) – DATABASE – IRB Committee Member Profile (in eIRB+).
- 3.2 IRB staff members carry out these procedures.

## 4 PROCEDURE

- 4.1 For internal IRBs:
  - 4.1.1 For each IRB member who will no longer serve as an IRB member, prepare an 2.304 (HRP-561) - LETTER: IRB Member Thank You. Have the letter signed by the IO or designee and send to the former IRB members.
  - 4.1.2 Unregister the IRB with OHRP<sup>1</sup>.
  - 4.1.3 Remove the IRB from the FWA<sup>2</sup>.
  - 4.1.4 Remove members from 2.306 (HRP-601) – DATABASE – IRB Committee Member Profile (in eIRB+).
  - 4.1.5 Remove the individual's Committee Member role in the system.
  - 4.1.6 File:
    - 4.1.6.1 2.306 (HRP-601) - DATABASE IRB Committee Member Profile (in eIRB+).
    - 4.1.6.2 FWA.
    - 4.1.6.3 2.304 (HRP-561) - LETTER: IRB Member Thank You.
- 4.2 For external IRBs, follow the requirements of the inter-institutional agreement or contract.

## 5 MATERIALS

- 5.1 2.304 (HRP-561) - LETTER - IRB Thank You.
- 5.2 2.306 (HRP-601) - DATABASE – IRB Committee Member Profile (in eIRB+).

## REFERENCES

- 5.3 45 CFR §46.107, 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5).
- 5.4 21 CFR §56.107, 21 CFR §56.115(a)(5).

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

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