



SOP: IRB Removal

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1 PURPOSE

- 1.1 This procedure establishes the process to remove a Northwestern University IRB panel or discontinue Northwestern University's reliance on an external IRB for the review of human subjects research.
- 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 the Office for Human Research Protections (OHRP) and the Federalwide assurance (FWA) is updated (if needed).

2 PREVIOUS VERSION

- 2.1 Revised from previous version dated 08/01/2015

3 POLICY

- 3.1 The Institutional Official or Designee (e.g. the Executive Director, IRB Office) in conjunction with the IRB Office Managers determines when a Northwestern University IRB panel or reliance on an external IRB is no longer needed.
- 3.2 The IRB that is being removed must be unregistered with OHRP and Northwestern University's FWA updated (if needed)
- 3.3 IRB rosters are maintained using the "DATABASE: IRB Roster (HRP-601)."
- 3.4 Removal of IRB Members from a Northwestern University IRB panel is conducted in accordance with SOP "IRB Membership Removal" (HRP-083)

4 RESPONSIBILITIES

- 4.1 IRB Office 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 on Northwestern University's IRB panel, prepare a "TEMPLATE LETTER: IRB Member Thank You (HRP-561)," signed by the Institutional Official, Executive Director, IRB Office or designee, and send to the former IRB members.
 - 5.1.2 Unregister the IRB with OHRP¹.
 - 5.1.3 Remove the IRB from the Federalwide assurance (FWA)².
 - 5.1.4 Remove members from "DATABASE: IRB Roster (HRP-601)."
 - 5.1.5 Remove the individual's Committee Member role in the Northwestern University electronic IRB system.
 - 5.1.6 File:
 - 5.1.6.1 DATABASE: IRB Roster (HRP-601)
 - 5.1.6.2 Federalwide assurance (FWA)
 - 5.1.6.3 TEMPLATE LETTER: IRB Member Thank You (HRP-561)
- 5.2 For external IRBs follow the requirements of the inter-institutional agreement or contract for termination of services.

6 MATERIALS

- 6.1 DATABASE: IRB Roster (HRP-601)
- 6.2 SOP: IRB Membership Removal (HRP-083)

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/>.

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6.3 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), 45 CFR 46 Subpart E.
- 7.2 21 CFR §56.107, 21 CFR §56.115(a)(5).