1 PURPOSE

1.1 This procedure establishes the process to form a new Northwestern University IRB panel, update the IRB registration of an existing IRB for the review of human participant research.

1.2 The process begins when the Institutional Official or designee determines the need for a new IRB or updated IRB registration.

1.3 The process ends when the IRB is registered with the Office for Human Research Protections (OHRP), the Federalwide assurance (FWA) is updated (if needed), and all IRB Panel members have completed training (if needed).

2 PREVIOUS VERSION

2.1 Revised from previous version dated 06/01/2023.

3 POLICY

3.1 The Institutional Official or Designee (e.g., the Executive Director, IRB Office), in conjunction with the appropriate IRB Office Associate Director or IRB Office Manager(s), determines: (1) when a new Northwestern University IRB panel or reliance on an external IRB is needed, (2) the type and scope of reviews that the new IRB will conduct and the frequency of the IRB panel meetings

3.2 The new Northwestern University IRB panel must be registered with OHRP and Northwestern University's FWA updated (as applicable) before the new IRB reviews research conducted or supported by the Department of Health and Human Services (HHS).

3.3 IRB rosters are maintained using the "DATABASE: IRB Roster (HRP-601)."

3.4 A FWA will be submitted or updated as follows:

- 3.4.1 To engage in human subjects research that is not exempt from the regulations, and is conducted or supported by any HHS agency.
- 3.4.2 To list the institution's legal components that operate under different names that will be covered by the FWA and the city and state or country where the component is located.
- 3.4.3 To designate all internal and external IRBs that will review research covered by the FWA.
- 3.4.4 Within 90 days after changes regarding the legal name of the institution, the Human Protections Administrator, or the Signatory Official.

3.5 FWAs are renewed every 5 years, even if no changes occur. Any renewal or update approved by OHRP begins a new 5-year effective period.

3.6 IRB registrations on file with HHS will be made or updated as follows:

- 3.6.1 If an IRB's contact or chairperson information changes, the IRB must revise its registration information within 90 days of the change.
- 3.6.2 If an IRB decides to review new types of FDA-regulated products (e.g., to review device studies if it only reviewed drug studies previously) or to stop reviewing clinical investigations regulated by FDA, this must be reported within 30 days of the change.
- 3.6.3 If an IRB decides to disband, this must be reported within 30 days of permanent cessation of the IRB's review of research.
- 3.6.4 An IRB is required to renew its registration and verify the required information every 3 years from the date of the last entry/change made to the registration information.

3.7 Addition of IRB Members to a new Northwestern University IRB panel is conducted in accordance with SOP: IRB Member Addition (Appointment and Reappointment (HRP-082)

3.8 Northwestern University will rely on an external IRB when there is an executed IRB Authorization Agreement and in accordance with SOP: External IRBs (HRP-092)

4 RESPONSIBILITIES

4.1 IRB Office staff members carry out these procedures.

4.2 The Institutional Official or designee (e.g., the Executive Director, IRB Office), in conjunction with the appropriate IRB Office Associate Directors or Manager(s), appoints IRB members, alternate members, IRB Chairs and Vice Chairs.

5 PROCEDURE

5.1 Determine from the Institutional Official or designee whether the IRB will conduct all reviews without limitation or will be limited to certain types of reviews.

5.2 For external IRBs:

5.2.1 Determine that the external IRB meets the required criteria and ensure that an IAA has been executed in accordance with SOP "External IRBs" (HRP-092) and that the IAA has been filed.

5.3 For internal IRBs:

5.3.1 Constitute the new IRB as follows:

5.3.1.1 At least 5 individuals to serve as IRB members.

5.3.1.2 Additional individuals to serve as alternate IRB members, if needed.

5.3.1.3 At least 1 of the individuals to be the IRB Chair.

5.3.1.4 At least one member whose primary concerns are in scientific areas, one member whose primary concerns are in nonscientific areas, and one member who is unaffiliated with the institution.

5.3.1.5 Use WORKSHEET: IRB Composition (HRP-304) and revise the selected individuals as needed to ensure that the IRB meets regulatory and organizational requirements.

5.3.2 Follow SOP: IRB Member Addition (Appointment and Reappointment) (HRP-082) for each IRB member.

5.3.3 Notify the IRB Office Executive Director and appropriate IRB Office Associate Director and or Manager(s) when all new IRB members have completed training.

5.3.4 Create the new IRB committee and add the individual Committee Member roles in the Northwestern University electronic IRB system.

5.3.5 Register the IRB with OHRP[1].

5.3.6 Add the new IRB to Northwestern University's Federalwide assurance (FWA)[2].

5.3.7 Notify the IO/OO or their designee with a summary of changes.

6 MATERIALS

6.1 DATABASE: IRB Roster (HRP-601)

6.2 FORM: IRB Member Information (HRP-202)

6.3 SOP: IRB Member Addition (Appointment and Reappointment) (HRP-082)

6.4 SOP: External IRBs (HRP-092)

6.5 TEMPLATE LETTER: IRB New Member Appointment (HRP-560)

6.6 WORKSHEET: IRB Composition (HRP-304)

7 REFERENCES

7.1 45 CFR §46.107, 45 CFR §46.103(b), 45 CFR §46.115(a)(5), 45 CFR 46, Subpart E.

7.2 21 CFR §56.106-107, 21 CFR §56.115(a)(5).

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[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/.