1 PURPOSE
1.1 This procedure establishes the process to form a new Northwestern University IRB panel or rely on an external IRB for the review of human subjects research.
1.2 The process begins when the Institutional Official or designee determines the need for a new IRB.
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.

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 appropriate IRB Office Manager(s) determines: (1) when a new Northwestern University IRB panel or reliance on an external IRB is needed and (2) the type and scope of reviews that the new IRB will conduct.
3.2 The new Northwestern University IRB panel that is being added must be registered with OHRP and Northwestern University’s FWA updated (as applicable) before it 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 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)
3.5 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 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 Select:
    5.3.1.1 At least five 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 one of the individuals to be the IRB chair.
  5.3.2 Follow “SOP: IRB Member Addition (Appointment and Reappointment)” (HRP-082) for each IRB member.
  5.3.3 Use “WORKSHEET: IRB Composition (HRP-304)” and revise the selected individuals as needed to ensure that the IRB meets regulatory and organizational requirements.
5.3.4 Notify the Executive Director, IRB Office and IRB manager when all new IRB members have completed training.
5.3.5 Create the new IRB committee and add the individual Committee Member roles in the Northwestern University electronic IRB system.
5.3.6 Register the IRB with OHRP1.
5.3.7 Add the new IRB to Northwestern University’s Federalwide assurance (FWA)2.

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)(3), 45 CFR §46.115(a)(5), 45 CFR 46, Subpart E.
7.2 21 CFR §56.107, 21 CFR §56.115(a)(5).

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