

SOP: IRB Formation

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1 PURPOSE

- 1.1 This procedure establishes the process to form or rely on a new IRB.
- 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, the federalwide assurance (FWA) is updated, and all members have completed training.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Administrative Updates

3 POLICY

- 3.1 IRB rosters are maintained using the “DATABASE: IRB Roster (HRP-601)” or equivalent.

4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.
- 4.2 The Institutional Official or designee appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., 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. Indicate this on the “IRB Scope” tab of the “DATABASE: IRB Roster (HRP-601)” or equivalent.
 - 5.1.1 Update the federalwide assurance (FWA) with the new IRB.
File the federalwide assurance (FWA).
 - 5.1.2 Select:
 - 5.1.2.1 At least five individuals to serve as IRB members.
 - 5.1.2.2 Additional individuals to serve as alternate IRB members, if needed.
 - 5.1.2.3 At least one of the individuals to be the IRB chair.
 - 5.1.3 Follow “SOP: IRB Member Addition” for each IRB member.
 - 5.1.4 Use “WORKSHEET: IRB Composition (HRP-304)” and revise the selected individuals as needed to ensure that the IRB is appropriately constituted.
 - 5.1.5 Notify the Institutional Official or designee and IRB director when all individuals have completed training.

6 MATERIALS

- 6.1 DATABASE: IRB Roster (HRP-601)
- 6.2 FORM: IRB Member Information (HRP-202)
- 6.3 SOP: IRB Member Addition (HRP-082)
- 6.4 TEMPLATE LETTER: IRB Member Appointment (HRP-560)
- 6.5 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).
- 7.2 21 CFR §56.107, 21 CFR §56.115(a)(5).