



SOP: IRB Formation

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HRP-080	06/19/2019	C.Gates	C.Gates	1 of 1

1 PURPOSE

- 1.1 This procedure establishes the process to form 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 (if needed), and all members have completed training.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None
- 2.2 Revisions for clarity and to remove references to external IRBs.

3 GUIDING PRINCIPLES

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

4 RESPONSIBILITIES

- 4.1 HSRO 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 newly formed 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).”
 - 5.1.1 File the agreement or contract if one exists.
- 5.2 For new internal IRBs:
 - 5.2.1 Select:
 - 5.2.1.1 At least five individuals to serve as IRB members.
 - 5.2.1.2 Additional individuals to serve as alternate IRB members, if needed.
 - 5.2.1.3 At least one of the individuals to be the IRB chair.
 - 5.2.2 Follow “SOP: IRB Member Addition” for each IRB member.
 - 5.2.3 Use “WORKSHEET: IRB Composition (HRP-304)” and revise the selected individuals as needed to ensure that the IRB is appropriately constituted.
 - 5.2.4 Notify the Executive Director, HSRO 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).