



**TITLE:** IRB Formation

**PURPOSE:** Outline the process to create a new IRB or rely on an external IRB

**RESPONSIBILITIES:** HSPP Staff  
The Organizational Official, in consultation with the HSPP Director, IRB Chairs, and Associate Vice President for Research Compliance and Policy appoints IRB members, alternate members, and IRB chairs.

**PROCEDURES:**

The Organizational Official or designee determines the need for a new IRB, either internal or external, and whether the new IRB will conduct reviews without limitation or will be limited to certain types of reviews.

- If appropriate, update IRB roster with the Office for Human Research Protection.

**For external commercial IRBs:**

- Consult the AAHRPP website and ensure that the commercial IRB is AAHRPP accredited. Non-accredited commercial IRBs should not be utilized.
- Update the FWA with the new IRB, if required.
- File the FWA.

**For internal IRBs:**

- Select:
  - At least five (5) individuals to serve as IRB members.
  - Additional individuals to serve as alternate IRB members, if needed.
  - The IRB chair and the IRB vice chair.
- Follow the process in the Operations Manual for IRB member appointments.
- Update the IRB roster.
- File the IRB roster, the Federalwide Assurance, and all checklists, résumés or curriculum vitae, and appointment letters.
- Notify the HSPP staff when all individuals have completed training.
- Update the HSPP website appropriately.

**MATERIALS:**

- D602 - IRB Roster
- W202 - IRB Member Information
- T560 - IRB Member Appointment
- W308 - IRB Composition
- Operations Manual

**REFERENCES:**

- 45 CFR §46.107, 45 CFR §46.103(b)(3), 45 CFR §46.115(a)(5), 45 CFR 46 Subpart E
- 21 CFR §56.107, 21 CFR §56.115(a)(5).
- 45 CFR 46, OHRP Frequently Asked Questions (FAQs) on IRB Registrations



**REVIEW/REVISIONS:** From 01/2014 version: Removed reference to updating IRB Scope on IRB roster per OHRP guidance on IRBs to be listed on the IRB roster; clarified external IRBs are commercial IRBs.

From 10/01/2010 version: Indicated that the Federalwide Assurance only needs to be updated if required; Removed hyperlink to guidance.

From 08/01/2011 version: Revised procedures to refer to Operations Manual; clarified responsibilities.

From 01/2014 version: Renumbered from P&P-080.