



HRP-080 | 5/13/2025 | Owner: A. Owner | Approver: B. Approver

## SOP: IRB Formation and Registration

### 1 PURPOSE

- 1.1 This procedure establishes the process to form a new IRB or update the OHRP IRB registration of an existing IRB.
- 1.2 The process begins when the Institutional Official/ Organizational Official (IO/OO) or designee determines the need for a new IRB or updated OHRP IRB registration.
- 1.3 The process ends when the IRB is registered, the federalwide assurance (FWA) is updated (if needed), and all members have completed training (if needed).

### 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

### 3 POLICY

- 3.1 IRB rosters are maintained using HRP-601 - DATABASE - IRB Roster.
- 3.2 A FWA will be submitted or updated as follows:
  - 3.2.1 To engage in human subjects research that is not exempt from the regulations, and is conducted or supported by any HHS agency.
  - 3.2.2 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.
  - 3.2.3 To designate all internal IRBs (or external IRBs that review the largest percentage of research if the institution does not have an internal IRB) that will review research covered by the FWA.
  - 3.2.4 Within 90 days after changes regarding the legal name of the institution, the Human Protections Administrator, or the Signatory Official.
- 3.3 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.
- 3.4 IRB registrations on file with OHRP will be made or updated as follows:
  - 3.4.1 To register any additional IRB before it is designated under an FWA and reviews research conducted or supported by HHS.
  - 3.4.2 Within 90 days after changes regarding the contact person who provided the IRB registration information, the IRB chairperson, or changes to the IRB membership roster.
  - 3.4.3 Within 30 days of the change if an FDA-regulated IRB decides to review additional types of FDA-regulated products (e.g., to review device studies if it only reviewed drug studies previously) or to discontinue reviewing clinical investigations regulated by FDA.
  - 3.4.4 Within 30 days of permanent cessation of the IRB's review of HHS-conducted or supported research when an institution disbands a registered IRB that it is operating.
  - 3.4.5 IRB registration must be renewed every 3 years, even if no changes occur. Any renewal or update accepted by OHRP begins a new 3-year effective period.

### 4 RESPONSIBILITIES

- 4.1 IRB staff members carry out these procedures.

- 4.2 The IO/OO or designee appoints IRB members, alternate members, IRB chairs, and if used, other officers (e.g., vice chairs.)

## 5 PROCEDURE

- 5.1 For new IRBs:
- 5.1.1 Determine from the IO/OO 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 HRP-601 - DATABASE - IRB Roster.
- 5.1.1.1 Select:
- 5.1.1.1.1 At least five individuals to serve as IRB members.
- 5.1.1.1.2 Additional individuals to serve as alternate IRB members, if needed.
- 5.1.1.1.3 At least one of the individuals to be the IRB chair.
- 5.1.1.2 Follow HRP-082 - SOP - IRB Membership Addition for each IRB member.
- 5.1.1.3 Use HRP-304 - WORKSHEET - IRB Composition and revise the selected individuals as needed to ensure that the IRB is appropriately constituted.
- 5.1.1.4 Notify the IRB manager when all individuals have completed training.
- 5.2 File a new FWA, or update an existing, by following the instructions available at the OHRP website: <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/fwais/index.html>
- 5.3 Register the new IRB, or update an existing IRB's OHRP registration as required by this policy, by following the instructions available at the OHRP website: <https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/irb-registration/new-irb-registration/index.html>.

## 6 MATERIALS

- 6.1 HRP-082 - SOP - IRB Membership Addition
- 6.2 HRP-202 - FORM - IRB Member Information
- 6.3 HRP-304 - WORKSHEET - IRB Composition
- 6.4 HRP-601 - DATABASE - IRB Roster

## 7 REFERENCES

- 7.1 45 CFR §46.103, 45 CFR §46.107, 45 CFR §46.108, 45 CFR §46.115(a)(5).
- 7.2 21 CFR §56.107, 21 CFR §56.115(a)(5).
- 7.3 AAHRPP elements I.1.A, II.1.A-C

**Commented [A1]:** Note: These statements apply to VA facilities only (not HRPPs that review on behalf of a VA facility).