1 PURPOSE

1.1 This SOP 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 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 IRB New Member Orientation (if needed).

2 REVISIONS FROM PREVIOUS VERSION

2.1 Revised from the 5/30/2017 version.

3 SOP Statement

3.1 Internal IRB rosters are maintained using the: IRB Roster Sheet.

3.2 IRB registrations on file with OHRP will be made or updated as follows:

- 3.2.1 To register any additional IRB before it is designated under an FWA and reviews research conducted or supported by HHS.
- 3.2.2 Within 90 days after changes regarding the contact person who provided the IRB registration information or the IRB chairperson.
- 3.2.3 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.

4 RESPONSIBILITIES

4.1 IRB/HRPP 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 For new IRBs:

- 5.1.1 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 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;
    - 5.1.1.1.4 A Vice Chair may be appointed to support the role of the IRB chair;
- 5.1.2 Follow HRP-082 - SOP - IRB Membership Addition for each IRB member.
- 5.1.3 Use HRP-304 - WORKSHEET - IRB Composition and revise the selected individuals as needed to ensure that the IRB is appropriately constituted.
- 5.1.4 Notify the HRPP Director when all individuals have completed IRB New Member Orientation.
- 5.1.5 Create the new committee in the electronic system.
- 5.1.6 Once orientation is completed, add committee members to the system.
- 5.1.7 Assign the Expedited Review label to any designees eligible to conduct non-committee reviews.

5.2 Register the new IRB, or update an existing IRB’s OHRP registration by following the instructions available at the OHRP website: Register IRBs & Obtain FWAs | HHS.gov

6 MATERIALS

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

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