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 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 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 HRPP Director when all individuals have completed training.

5.1.1.5 Using the “Create Committee” SmartForm, create the new committee in the system.

5.1.1.6 Once training is completed, add committee members to the system with the Committee Member role.

5.1.1.7 Assign any designees eligible to conduct non-committee reviews using the “Update Eligible Designated Reviewers” activity.

5.2 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