



SOP: Designated Reviewers

NUMBER	APPROVED BY	EFFECTIVE DATE	PAGE
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1 PURPOSE

- 1.1 This procedure establishes the process for an IRB Chair to designate IRB Members who can conduct Non-Committee Reviews.
- 1.2 The process begins when the IRB Manager appoints a new IRB Member to an IRB Panel.
- 1.3 The process ends when IRB Office staff record the IRB Member in the IRB roster as approved to conduct Non-Committee Reviews.

2 PREVIOUS VERSION

- 2.1 Revised from previous version dated 11/22/2018

3 POLICY

- 3.1 IRB rosters are maintained using the "DATABASE: IRB Roster (HRP-601)."
- 3.2 The IRB Office staff notify the IRB Chair when the IRB Manager appoints a new IRB Member to a Panel and lists the Member on the IRB Roster. All IRB Members listed on the IRB Roster are considered IRB Chair appointed Designated Reviewers.
- 3.3 IRB Members/alternates are appointed for a three-year term. Members/alternates are eligible for re-appointment at the end of their term.

4 RESPONSIBILITIES

- 4.1 The IRB Chair and IRB Office staff members carry out these procedures.
- 4.2 The IRB Office staff is responsible for determining specific expertise needed and assigning submissions to Experienced IRB Members who can conduct Non-Committee Reviews.

5 PROCEDURE

- 5.1 Have the individual complete the "FORM: IRB Member Information (HRP-202)" and obtain a copy of the individual's resume or curriculum vita.
- 5.2 IRB Office staff conduct the process for appointing or re-appointing the IRB Member in accordance with SOP "IRB Member Addition (Appointment and Re-Appointment)", HRP-082.
- 5.3 Verify that the IRB Member is an Experienced IRB Member.
- 5.4 Update the "DATABASE: IRB Roster (HRP-601)" to indicate that the IRB Member is a Designated Reviewer.
- 5.5 Review list of IRB Members designated to conduct Non-Committee Reviews in the "Assign Designated Reviewer" activity in eIRB+.
- 5.6 Use the "Update Eligible Designated Reviewers" activity to indicate that the IRB Member is a Designated Reviewer.

6 MATERIALS

- 6.1 SOP: IRB Member Addition (Appointment and Reappointment) (HRP-082)
- 6.2 FORM: IRB Member Information (HRP-202)
- 6.3 TEMPLATE LETTER: IRB Member Appointment (HRP-560)
- 6.4 DATABASE: IRB Roster (HRP-601)

7 REFERENCES

- 7.1 21 CFR §56.110(b).
- 7.2 45 CFR §46.110(b).