



SOP: Designated Reviewers				
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1 PURPOSE

- 1.1 This procedure establishes the process to appoint IRB members to the role of designated reviewer as described in 21 CFR 56.110 and 45 CFR 46.110.
- 1.2 The process begins when the Institutional Official, or designee, notes the need to appoint an experienced IRB member to serve as a designated reviewer.
- 1.3 The process ends when the Chair has designated the member and the member is notified.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 GUIDING PRINCIPLES

- 3.1 Experienced IRB members may serve as a designated reviewer.

4 RESPONSIBILITIES

- 4.1 The IRB Chair selects designated reviewers.
- 4.2 HSRO staff members carries out the remaining procedures.

5 PROCEDURE

- 5.1 Determine from the Institutional Official when an additional designated reviewer is needed.
- 5.2 Request the IRB Chair to appoint an experienced IRB member to serve as a designated reviewer.
- 5.3 Notify the member appointed by the Chair of their role as a designate reviewer via email or letter.
- 5.4 Provide training on the conduct of expedited review for the individual.
- 5.5 Complete a TEMPLATE LETTER (HRP-000) Appointment of Designated Reviewer (HRP-062), or equivalent and send to the Member.
- 5.6 Notify the Executive Director, HSRO, when the training is complete

6 Maintain the following in the Regulatory Binder – IRB Roster:

- 6.1 TEMPLATE LETTER (HRP-000), or equivalent
- 6.2 Training sign-in sheet

7 MATERIALS

- 7.1 None

8 REFERENCES

- 8.1 21 CFR 56.110 and 45 CFR 46.110