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