

	<b>SOP: Designated Reviewers</b>		
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## 1 PURPOSE

- 1.1 This SOP establishes the process for an IRB chair to designate Experienced IRB Members who can conduct Non-Committee Review.
- 1.2 The process begins when the HRPP Director notifies the IRB chair that a new IRB Member is eligible to become a Designated Reviewer.
- 1.3 The process ends when the HRPP/IRB staff record the IRB Member in the electronic system as approved to conduct Non-Committee Reviews.

## 2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Revised from 5/30/2017 version.

## 3 SOP Statement

- 3.1 Designated Reviewers carry out the review of research that is eligible for expedited review or other non-committee reviews in accordance with HRP-032 - SOP - Non-Committee Review Conduct

## 4 RESPONSIBILITIES

- 4.1 The IRB Chair and the HRPP/IRB Staff carry out these procedures.
- 4.2 The HRPP/IRB Staff is responsible for determining specific expertise needed and assigning submissions to Experienced IRB Members who can conduct Expedited Review and other Non-Committee Reviews.

## 5 PROCEDURE

- 5.1 To add a Designated Reviewer:
  - 5.1.1 Review the IRB roster and ensure that the proposed individual is an IRB member.
  - 5.1.2 Verify that the IRB member is experienced by having been a member of any IRB for a period of at least one year; or
    - 5.1.1. The HRPP Director has identified a new IRB member as being eligible for designated review and notifies the IRB chair and the IRB confirms that the IRB member has demonstrated sufficient experience in and knowledge of the criteria for approval and conducting IRB reviews.
- 5.2 To remove an IRB members designation as a Designated Reviewer no criteria need be followed.
  - 5.2.1 Notify the IRB or HRPP staff member managing the electronic system and IRB Roster of a decision to add or remove an IRB member as a designated reviewer and have the staff member update the IRB roster.
  - 5.2.2 Notify the IRB member of the decision.
- 5.3 To remove an IRB member from the IRB, refer to HRP-083 - IRB Membership Removal

## 6 MATERIALS

- 6.1 HRP-601 - IRB Roster
- 6.2 HRP-032 - SOP - Non-Committee Review
- 6.3 HRP-083 - IRB Membership Removal

## 7 REFERENCES

- 7.1 21 CFR §56.110(b).
- 7.2 45 CFR §46.110(b).
- 7.3 AAHRPP I.1.A, I-9, II.2.A, II.2.B, II.2.D, II.2.F, F-II.2.F.3