

	OIA-030 SOP: Designated Reviewers				
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1 PURPOSE

- 1.1 This procedure establishes the process for an IRB chair to designate IRB members as designated reviewers who can conduct non-committee reviews.
- 1.2 The process begins after an experienced IRB member is identified by Office of IRB Administration (OIA) staff or an IRB chair as meeting requirements to conduct non-committee reviews.
- 1.3 The process ends when the IRB member has been designated to conduct non-committee reviews.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 REQUIREMENTS

- 3.1 IRB rosters are maintained using the *OIA-601 DATABASE: IRB Roster*, or equivalent.
- 3.2 IRB members may be members of OIA staff who have completed training with their supervisors or designees prior to being selected to perform non-committee reviews. While specific training will be tailored to each individual based on current knowledge, expertise, and job duties, this training will, at a minimum, include:
 - 3.2.1 Review of *OIA-310 WORKSHEET: Human Research Determination*
 - 3.2.2 Review of *OIA-311 WORKSHEET: Engagement Determination*
 - 3.2.3 Review of *OIA-312 WORKSHEET: Exemption Determination*
 - 3.2.4 Review of *OIA-313 WORKSHEET: Eligibility for Review Using the Expedited Procedure*
 - 3.2.5 Review of *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*
 - 3.2.6 Review of *OIA-314B WORKSHEET: Requirements for Informed Consent*
- 3.3 IRB members who are not members of OIA staff must be experienced IRB members in order to be considered qualified to perform non-committee reviews.

4 RESPONSIBILITIES

- 4.1 OIA staff members and IRB chairs carry out these procedures.

5 PROCEDURE

- 5.1 When an IRB member who is a member of OIA staff will conduct non-committee reviews:
 - 5.1.1 OIA director or designee determines which OIA staff who are also IRB members may perform non-committee reviews and should be a designated reviewer.
 - 5.1.2 Upon completion of the training and with concurrence from the OIA staff members' supervisors that they are experienced IRB members, the OIA staff member's supervisor will draft and send *OIA-564 TEMPLATE LETTER: Designated Reviewer Appointment*, or equivalent, to the OIA director.
 - 5.1.3 The OIA Director will review the letter, considering the qualifications and training of the OIA staff member being considered for designated reviewer appointment.
 - 5.1.3.1 If the OIA director agrees the OIA staff member is an experienced IRB member, the director will sign the letter and return to OIA staff.
 - 5.1.3.2 If the OIA director does not agree that the OIA staff member is an experienced IRB member, the director will respond to OIA staff with stated concerns.
 - 5.1.4 Once the *OIA-564 TEMPLATE LETTER: Designated Reviewer Appointment*, or equivalent, is signed:
 - 5.1.4.1 Provide a copy to the OIA staff member.
 - 5.1.4.2 File a copy in the OIA records.
 - 5.1.4.3 Update the *OIA-601 DATABASE: IRB Roster*, or equivalent, to indicate that the OIA staff member is a designated reviewer.
- 5.2 When an IRB member who is not a member of OIA staff will conduct non-committee reviews:
 - 5.2.1 OIA staff will obtain the name of the IRB member from OIA leadership (i.e., an OIA supervisor, assistant director, medical director, or director) and/or IRB chair(s) to be designated to conduct non-committee reviews.
 - 5.2.2 OIA staff will draft and send *OIA-564 TEMPLATE LETTER: Designated Reviewer Appointment*, or equivalent, to the IRB chair(s) for review and signature.

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- 5.2.3 IRB chair(s) will review the letter, considering the qualifications and experience of IRB member being considered for designated reviewer appointment.
 - 5.2.3.1 If IRB chair(s) agrees the IRB member is an experienced IRB member, the chair will sign the letter and return to OIA staff.
 - 5.2.3.2 If IRB chair(s) does not agree that the IRB member is an experienced IRB member, the chair will respond to OIA staff with stated concerns.
- 5.2.4 Once the *OIA-564 TEMPLATE LETTER: Designated Reviewer Appointment*, or equivalent, is signed:
 - 5.2.4.1 Provide a copy to the IRB member.
 - 5.2.4.2 File a copy in the OIA records.
 - 5.2.4.3 Update the *OIA-601 DATABASE: IRB Roster*, or equivalent, to indicate that the IRB member is a designated reviewer.

6 MATERIALS

- 6.1 *OIA-001 SOP: Definitions*
- 6.2 *OIA-310 WORKSHEET: Human Research Determination*
- 6.3 *OIA-311 WORKSHEET: Engagement Determination*
- 6.4 *OIA-312 WORKSHEET: Exemption Determination*
- 6.5 *OIA-313 WORKSHEET: Eligibility for Review Using the Expedited Procedure*
- 6.6 *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*
- 6.7 *OIA-314B WORKSHEET: Requirements for Informed Consent*
- 6.8 *OIA-564 TEMPLATE LETTER: Designated Reviewer Appointment*
- 6.9 *OIA-601 DATABASE: IRB Roster*

7 REFERENCES

- 7.1 [21 CFR 56.110\(b\)](#)
- 7.2 [45 CFR 46.110\(b\)](#)