

 INSTITUTIONAL REVIEW BOARD ADMINISTRATION	OIA-060 SOP: Assessment of the OIA				
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1 PURPOSE

- 1.1 This procedure establishes the process to conduct an assessment of the Office of IRB Administration (OIA).
- 1.2 The process begins upon request by the Institutional Official, the Vice Chancellor for Research, or the Chancellor.
- 1.3 The process ends when all evaluations have been completed and communicated to those evaluated.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 REQUIREMENTS

- 3.1 The OIA is evaluated periodically, when requested by the Institutional Official, the Vice Chancellor for Research, or the Chancellor.¹

4 RESPONSIBILITIES

- 4.1 The OIA staff ensure completion of these procedures.

5 PROCEDURE

- 5.1 The OIA director or designee evaluates the following resources provided to the OIA and makes adjustments or requests additional resources as necessary. A copy of the evaluation is provided to the institutional official or designee.
 - 5.1.1 Space
 - 5.1.2 Educational program
 - 5.1.3 Legal counsel
 - 5.1.4 IRB membership and availability to conduct review taking into account any conflicting interests and expertise.
 - 5.1.4.1 As a part of this evaluation, IRB members will be asked to review the *OIA-202 FORM: IRB Member Information*, or equivalent, previously provided to OIA and make any updates as necessary or confirm that the information remains current.
 - 5.1.5 Quality improvement plan
 - 5.1.6 Technology equipment and support
 - 5.1.7 Staff
- 5.2 Evaluate whether the number of IRBs is appropriate to the volume and types of research reviewed.
 - 5.2.1 Provide a copy of the evaluation to the institutional official or designee.
 - 5.2.2 If the number of IRBs is not appropriate to the volume and types of research reviewed, work with the institutional official or designee to modify the IRB structure.
- 5.3 The OIA director, OIA assistant director, or designee evaluates the knowledge, skills, and performance of each IRB member who is not a chair or vice chair. This may be done in consultation with the IRB chair(s) or IRB vice chair(s).
 - 5.3.1 OIA staff may use *OIA-445 CHECKLIST: IRB Member Evaluation*, or equivalent, to complete the evaluation.
 - 5.3.2 Provide each IRB member with a copy of their evaluation and an opportunity to provide feedback regarding their evaluation.
 - 5.3.3 If feedback is provided, consider whether any new information has been provided that warrants a change to the evaluation.
 - 5.3.3.1 If a change is warranted, make the change(s) and repeat step 5.3.2.
 - 5.3.3.2 If a change is not warranted, proceed to 5.3.4.
 - 5.3.4 Provide a copy of the evaluation to the institutional official or designee.
 - 5.3.5 Send a copy of the *OIA-562 TEMPLATE LETTER: IRB Member Appreciation*, or equivalent, to the IRB member's supervisor, as applicable.

¹ Sections 5.1.4.1, 5.3, and 5.4 of this procedure will not be completed in 2024 (for the calendar year 2023 evaluation) even if assessment is requested in 2024 since members will not have been previously informed of the evaluation expectations and will have very recently provided their member information.

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- 5.3.6 If needed, work with each IRB member to develop a performance improvement plan. The plan, including the timeframe in which satisfactory performance is to be achieved, should take into account the individual's knowledge, skills, and performance that need to be improved.
- 5.4 The OIA director, OIA assistant director, or designee evaluates the knowledge, skills, and performance of each IRB chair and vice chair.
- 5.4.1 OIA staff may use *OIA-446 CHECKLIST: IRB Chair and Vice Chair Evaluation*, or equivalent, to complete the evaluation.
- 5.4.2 Provide each IRB chair or vice chair with a copy of their evaluation and an opportunity to provide feedback regarding their evaluation.
- 5.4.3 If feedback is provided, consider whether any new information has been provided that warrants a change to the evaluation.
- 5.4.3.1 If a change is warranted, make the change(s) and repeat step 5.4.2.
- 5.4.3.2 If a change is not warranted, proceed to 5.4.4.
- 5.4.4 Provide a copy of the evaluation to the institutional official or designee.
- 5.4.5 Send a copy of the *OIA-562 TEMPLATE LETTER: IRB Member Appreciation*, or equivalent, to the IRB chair's or vice chair's supervisor, as applicable.
- 5.4.6 If needed, work with each IRB chair or vice chair to develop a plan to improve the individual's knowledge, skills, and performance.
- 5.5 Use the *OIA-304 WORKSHEET: IRB Composition*, or equivalent, to evaluate whether the composition of the IRB meets regulatory and institutional requirements.
- 5.5.1 Provide a copy of the evaluation to the institutional official or designee.
- 5.5.2 If the composition of any IRB does not meet regulatory and institutional requirements, work with the institutional official or designee to modify the IRB composition.
- 5.6 Check the last date each IRB was registered. If more than 2 years, update the IRB Organization (IORG) registration.²
- 5.7 Check the last date the federalwide assurance (FWA) was updated or renewed. If more than 4 years, update/renew the federalwide assurance (FWA).³

6 MATERIALS

- 6.1 *OIA-001 SOP: Definitions*
- 6.2 *OIA-202 FORM: IRB Member Information*
- 6.3 *OIA-304 WORKSHEET: IRB Composition*
- 6.4 *OIA-445 CHECKLIST: IRB Member Evaluation*
- 6.5 *OIA-446 CHECKLIST: IRB Chair and Vice Chair Evaluation*
- 6.6 *OIA-562 TEMPLATE LETTER: IRB Member Appreciation*
- 6.7 *OIA-602 DATABASE: Investigator Assistance Improvement Assessment*
- 6.8 Electronic submission system reports
- 6.9 Minutes of convened IRB meetings

7 REFERENCES

- 7.1 None

² See <http://www.hhs.gov/ohrp/assurances/>. Use the Web site: <http://ohrp.cit.nih.gov/efile/>.

³ See <http://www.hhs.gov/ohrp/assurances/>. Use the Web site: <http://ohrp.cit.nih.gov/efile/>.