

SOP: Annual Evaluations of the HRPP

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1 PURPOSE

- 1.1 This procedure establishes the process to conduct annual evaluations of the human research protection program.
- 1.2 The process begins the first business day of each June.
- 1.3 The process ends when all evaluations have been completed and communicated to those evaluated.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Updated section 3.2 with additional procedural language.

3 POLICY

- 3.1 The human research protection program is evaluated annually.
- 3.2 The subject outreach program for enhancing the understanding of subjects, prospective subjects, and communities is accomplished using multiple resources, including clinic-based research brochures (BROCHURE: SHOULD I TAKE PART IN RESEARCH [HRP-104], information on the Office of Research Website, outreach with the Community Engagement Program, and input from the Research and Education Community Advisory Board (RECAB).

4 RESPONSIBILITIES

- 4.1 IRB staff ensure completion of these procedures.

5 PROCEDURE

- 5.1 Have the Institutional Official or designee evaluate the following resources provided to the human research protection program and make adjustments as part of the budgeting process.
 - 5.1.1 Space
 - 5.1.2 HRPP educational program
 - 5.1.3 Legal counsel
 - 5.1.4 Conflicts of interests
 - 5.1.5 Quality improvement plan
- 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 Have the IRB chair or IRB director evaluate the knowledge, skills, and performance of each regular and alternate IRB member.
 - 5.3.1 Provide a copy of the evaluation to the Institutional Official or designee.
 - 5.3.2 Provide each IRB member with a copy of his or her evaluation.
 - 5.3.3 Send a copy of the "TEMPLATE LETTER: IRB Member Appreciation (HRP-562)" or equivalent to the IRB member's supervisor.
 - 5.3.4 If needed, work with each IRB member to develop a plan to improve the individual's knowledge, skills, and performance.
- 5.4 Have the Institutional Official or designee evaluate the knowledge, skills, and performance of each IRB chair.
 - 5.4.1 Provide a copy of the evaluation to the Institutional Official or designee.
 - 5.4.2 Provide each IRB chair with a copy of his or her evaluation.
 - 5.4.3 If needed, work with each IRB chair to develop a plan to improve the individual's knowledge, skills, and performance.
- 5.5 Follow the Human Resources annual employee evaluation process to evaluate the knowledge, skills, and performance of IRB staff.
 - 5.5.1 Provide a copy of the evaluation to the Institutional Official or designee.
 - 5.5.2 Provide each IRB staff with a copy of his or her evaluation.
 - 5.5.3 If needed, work with each IRB staff person to develop a plan to improve the individual's knowledge, skills, and performance.

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- 5.6 Use the “WORKSHEET: IRB Composition (HRP-304)” to evaluate whether the composition of the IRB meets regulatory and institutional requirements.
 - 5.6.1 Provide a copy of the evaluation to the Institutional Official or designee.
 - 5.6.2 If the composition of an IRB does not meet regulatory and institutional requirements, work with the Institutional Official or designee to modify the IRB composition.
- 5.7 Evaluate the subject outreach plan.
 - 5.7.1 Provide a copy of the evaluation to the Institutional Official or designee.
 - 5.7.2 If the subject outreach program is not meeting institutional goals, work with the Institutional Official or designee to modify the plan.
- 5.8 Check when the last time each IRB was registered. If more than 2 years, update the registration.¹
- 5.9 Check when the last time the federalwide assurance (FWA) was updated or renewed. If more than 4 years, update/renew the federalwide assurance (FWA).²

6 MATERIALS

- 6.1 BROCHURE: Should I Take Part in Research (HRP-104)
- 6.2 TEMPLATE LETTER: IRB Member Appreciation (HRP-562)
- 6.3 WORKSHEET: IRB Composition (HRP-304)

7 REFERENCES

- 7.1 None

¹ See <http://www.hhs.gov/ohrp/assurances/>. Use the Web site: <http://ohrp.cit.nih.gov/efile/>.

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