

SOP: Annual HRPP Evaluations				
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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 None

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 by making the document “BROCHURE: Should I Take Part in Research (HRP-104)” available to the patient population.

4 RESPONSIBILITIES

- 4.1 IRB staff ensure completion of these procedures.

5 PROCEDURE

- 5.1 Have the Organizational 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 Organizational 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 Organizational Official or designee to modify the IRB structure.
- 5.3 Have the IRB chair or IRB manager evaluate the knowledge, skills, and performance of each regular and alternate IRB member.
 - 5.3.1 Provide a copy of the evaluation to the Organizational 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)” 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 Organizational Official or designee evaluate the knowledge, skills, and performance of each IRB chair.
 - 5.4.1 Provide a copy of the evaluation to the Organizational 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 Organizational 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 organizational requirements.
 - 5.6.1 Provide a copy of the evaluation to the Organizational Official or designee.
 - 5.6.2 If the composition of an IRB does not meet regulatory and organizational requirements, work with the Organizational Official or designee to modify the IRB composition.
 - 5.6.3 composition.
- 5.7 Evaluate the subject outreach plan.
 - 5.7.1 Consider the following areas when evaluating the outreach plan:
 - 5.7.1.1 Whether the existing scope and content of HRPP outreach materials continue to be adequate;
 - 5.7.1.2 Whether modifications to existing outreach materials are necessary;
 - 5.7.1.3 Whether or not the HRPP’s existing materials are being regularly utilized by the IRB Office or by members of the research community in their own interaction with the communities in which they conduct research;
 - 5.7.1.4 Whether there are new opportunities to provide outreach activities to the community, and;
 - 5.7.1.5 Whether additional information is needed from the research community to assess the extent to which outreach materials are used and outreach activities take place.
 - 5.7.2 Provide a copy of the evaluation to the Organizational Official or designee.
 - 5.7.3 If the subject outreach program is not meeting organizational goals, work with the Institutional Official or designee to modify the plan. Modifications may include, but are not limited to:
 - 5.7.3.1 Modifying existing outreach materials;
 - 5.7.3.2 Developing new materials;
 - 5.7.3.3 Surveying the research community to identify and participate in additional outreach opportunities, and;
 - 5.7.3.4 Working directly with community organizations to identify and participate in additional outreach opportunities.
- 5.8 Review “SOP: IRB Formation” (HRP-080) to determine if IRB registration requires updating.¹ Check when the last time the federalwide assurance (FWA) was updated or renewed. If more than 2 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)
- 6.4 SOP: IRB Formation (HRP-080)

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/>.