



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 (HRPP).
- 1.2 The process begins the first business day of each September.
- 1.3 The process ends when all evaluations have been completed and communicated to those evaluated.

2 PREVIOUS VERSION

- 2.1 Revised from previous version dated 03/15/2019.

3 POLICY

- 3.1 The HRPP is evaluated annually.
- 3.2 During a Program Review year for the IRB Office, the key components of the HRPP evaluation are satisfied through the Program Review process.
- 3.3 The subject outreach program for enhancing the understanding of subjects, prospective subjects, and communities is accomplished by making resources pertaining to research participation and rights of human research participants available to the community on the IRB Office website.

4 RESPONSIBILITIES

- 4.1 IRB Office staff ensure completion of these procedures.

5 PROCEDURE

- 5.1 Have the Vice President for Research, Institutional Official/ Organizational Official (IO/OO) or designee evaluate the resources provided to the HRPP and make adjustments as part of the budgeting process.
- 5.2 Verify that the federalwide assurance (FWA) has been updated/renewed with OHRP within the last five years.¹
- 5.3 Evaluate whether the number of IRBs is appropriate to the volume and types of research reviewed.
 - 5.3.1 Provide a copy of the evaluation to the IO/OO or designee and if appropriate, work with the IO/OO or designee to modify the IRB structure so that it is appropriate to the volume and types of research reviewed.
- 5.4 Use the “WORKSHEET: IRB Composition (HRP-304)” to evaluate whether the composition of the IRB meets regulatory and Institutional requirements.
 - 5.4.1 Provide a copy of the evaluation to the Institutional Official or designee and if appropriate, work with the Institutional Official or designee to modify the IRB composition so that it meets the regulatory and Institutional requirements.
- 5.5 Verify that the IRB registrations have been updated with OHRP within the past year.²
- 5.6 Review “SOP: IRB Formation” (HRP-080) to determine if IRB registration requires
- 5.7 Have each IRB member with appointment periods ending soon (e.g., within 3 months of appointment term end date) complete the TEMPLATE: IRB Panel Member 360 Survey (HRP-559) (self-evaluation, chair evaluation, and staff evaluation).
- 5.8 Have each IRB chair evaluate the knowledge, skills, and performance of each regular and alternate IRB member, in conjunction with the IRB member’s reappointment assessment, which is scheduled for every 3 years.

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

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- 5.8.1 Provide a summary of the evaluations completed during the current year to the IO/OO or designee and if appropriate, work with each IRB member to develop a plan to improve the individual's knowledge, skills, and performance.
- 5.8.2 Provide each IRB member with a copy of his or her evaluation letter.
- 5.9 Have the IRB Office Executive Director or designee evaluate the knowledge, skills, and performance of each IRB chair, in conjunction with the IRB Chair's reappointment assessment, which is scheduled for every 3 years.
 - 5.9.1 Provide a summary of the evaluation to the IO/OO or designee, and if appropriate, work with each IRB chair to develop a plan to improve the individual's knowledge, skills, and performance.
 - 5.9.2 Provide each IRB chair with a copy of his or her evaluation letter.
- 5.10 Follow the Human Resources annual employee evaluation process to evaluate the knowledge, skills, and performance of IRB Office staff.
 - 5.10.1 Provide each IRB Office staff person with electronic access to his or her evaluation and if appropriate, work with each IRB Office staff member to develop a plan to improve the individual's knowledge, skills, and performance.
- 5.11 Have the IRB Office Executive Director or designee evaluate the HRPP education program and its resources to determine if the content is appropriate.
- 5.12 Evaluate the subject outreach program.
 - 5.12.1 Provide a copy of the evaluation to the IO/OO or designee.
 - 5.12.2 Consider the following areas when evaluating the outreach plan:
 - 5.12.2.1 Whether the existing scope and content of HRPP outreach materials continue to be adequate;
 - 5.12.2.2 Whether modifications to existing outreach materials are necessary;
 - 5.12.2.3 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;
 - 5.12.2.4 Whether there are new opportunities to provide outreach activities to the community, and;
 - 5.12.2.5 Whether additional information is needed from the research community to assess the extent to which outreach materials are used and outreach activities take place.
 - 5.12.3 If the subject outreach program is not meeting institutional goals, work with the Institutional Official or designee to modify the plan. Modifications may include, but are not limited to:
 - 5.12.3.1 Modifying existing outreach materials;
 - 5.12.3.2 Developing new materials;
 - 5.12.3.3 Surveying the research community to identify and participate in additional outreach opportunities, and;
 - 5.12.3.4 Working directly with community organizations to identify and participate in additional outreach opportunities.
- 5.13 The Conflict of Interest Office and the Office of General Counsel are separate, independent entities from the IRB Office. However, as part of the HRPP program, the Institutional Official routinely collaborates with both offices to facilitate discussion and address concerns.

6 MATERIALS

- 6.1 WORKSHEET: IRB Composition (HRP-304)
- 6.2 SOP: IRB Panel Member 360 Evaluation and Re-Appointment Procedure (HRP-062)
- 6.3 SOP: IRB Formation (HRP-080)
- 6.4 TEMPLATE: IRB Panel Member 360 Survey (HRP-559)



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7 REFERENCES

7.1 None