

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 each June and continues through August annually. The process may be extended to accommodate assessment completion, at discretion of the AVP for RRA.
- 1.3 The process ends when all evaluations have been completed and communicated to those evaluated.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 8.21.23.

3 POLICY

- 3.1 The Human Research Protection Program is evaluated annually.
- 3.2 The human research outreach program for enhancing the understanding of subjects, prospective subjects, and communities is accomplished by making informational resources pertaining to research participation and rights of research participants available to the community via the Human Research Protection Program website.

4 RESPONSIBILITIES

- 4.1 HRPP leadership and IRB staff ensure completion of these procedures.

5 PROCEDURE

- 5.1 Have the Assistant Vice President for Research Regulatory Affairs or designee evaluate the following resources provided to the Human Research Protection Program and adjust as part of the budgeting process.
 - 5.1.1 Space – physical and virtual – and office equipment
 - 5.1.2 HRPP educational program
 - 5.1.3 Availability of legal counsel and/or consultants
 - 5.1.4 Conflicts of interest
 - 5.1.5 Quality assessment and quality improvement activities
 - 5.1.6 Communicate the results of the evaluation to the IO or designee.
Have the Assistant Vice President for Research Regulatory Affairs or designee evaluate whether the number of IRBs is appropriate to the volume and types of research reviewed.
 - 5.1.7 Communicate the evaluation to the IO or designee.
 - 5.1.8 If the number of IRBs is not appropriate to the volume and types of research reviewed, work with the IO or designee to modify the IRB structure.
Have the HRPP Director or designee annually evaluate the knowledge, skills, and performance of each IRB chair and IRB Vice Chair.
 - 5.1.9 Document and archive a copy use of the evaluation worksheet and self-assessment in a guided conversation on OneDrive.
 - 5.1.10 Communicate the aggregate results of the evaluation to each IRB chair and IRB Vice Chair and the IO or designee.
 - 5.1.11 If needed, work with each IRB chair or IRB Vice Chair to develop a plan to improve the individual's knowledge, skills, and performance. Individual plans may include, but are not limited to, additional education or training, mentorship, or removal as a Chair.
Have HRPP Director and IRB Training and Communications Manager or designee annually evaluate the performance of each regular and alternate IRB member.
 - 5.1.12 Document performance of each IRB member in HRPP reports.
 - 5.1.13 Communicate the aggregate results of IRB members to the AVP and IO or designee.

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- 5.1.14 If needed, work with IRB members to develop a plan to improve the individual's knowledge, skills, and performance. Individual plans may include, but are not limited to additional education or training, mentoring, tandem reviews, or removal from IRB membership.
- 5.2 Use 2.201 (HRP-304) - WORKSHEET - IRB Composition to evaluate whether the composition of the IRB meets regulatory and organizational requirements.
 - 5.2.1 Provide a copy of the evaluation to the IO or designee.
 - 5.2.2 If the composition of an IRB does not meet regulatory and organizational requirements, work with the IO or designee to modify the IRB composition.
 - 5.2.3 Send a copy of HRP-562 - LETTER - IRB Appreciation to the IRB member's supervisor. Have the Assistant Vice President for Research Regulatory Affairs or the employee's direct supervisor follow Rutgers University Human Resources annual employee evaluation process to evaluate the knowledge, skills, and performance of IRB staff. Use 12.204 (HRP-328) - WORKSHEET - Performance Evaluation for IRB Staff as part of the evaluation.
 - 5.2.4 Document the results of this evaluation as part of the annual employee evaluation process.
 - 5.2.5 Archive a copy of the evaluation in each IRB staff members personnel file consistent with Rutgers University Human Resources policy.
 - 5.2.6 Provide each IRB staff with a copy of his or her evaluation.
 - 5.2.7 If needed, work with each IRB staff person to develop a plan to improve the individual's knowledge, skills, and performance. Individual plans may include re-training, additional education, mentoring, tandem reviews or removal as an IRB member.
- 5.3 Have the HRPP Director, IRB Training and Communications Manager or designee evaluate the HRPP education program and its resources to determine if the content is appropriate.
- 5.4 Evaluate the subject outreach plan.
 - 5.4.1 Consider the following areas when evaluating the outreach plan:
 - 5.4.1.1 Whether the existing scope and content of HRPP outreach materials continue to be adequate;
 - 5.4.1.2 Whether modifications to existing outreach materials are necessary;
 - 5.4.1.3 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 interactions with the communities in which they conduct research;
 - 5.4.1.4 Whether there are new opportunities to provide outreach activities and/or materials to the community, and;
 - 5.4.1.5 Whether additional information is needed from the research community to assess the extent to which outreach materials are used and outreach activities take place.
 - 5.4.2 Communicate the evaluation to the IO or designee.
 - 5.4.3 If the subject outreach program is not meeting organizational goals, work with the QA&E Team and the HRPP Director to modify the plan. Modifications may include, but are not limited to:
 - 5.4.3.1 Modifying existing outreach materials;
 - 5.4.3.2 Developing new materials;
 - 5.4.3.3 Surveying the research community to identify and participate in additional outreach opportunities, and;
 - 5.4.3.4 Working directly with community organizations to identify and participate in additional outreach opportunities.



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5.5 Review 2.001 (HRP-080) - SOP - IRB Formation and Registration to determine if IRB registration requires updating.¹

5.6 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 1.006 (HRP-104) - BROCHURE - Should I Take Part in Research.

6.2 2.001 (HRP-080) - SOP - IRB Formation and Registration.

6.3 2.201 (HRP-304) - WORKSHEET - IRB Composition.

6.4 2.301-2.303 (HRP-560a, b, & c) - LETTERS - IRB Appointment.

6.5 2.305 (HRP-562) - LETTER - IRB Appreciation.

6.6 12.201 (HRP-326) - WORKSHEET- Performance Evaluation for IRB Chairs.

6.7 12.203 (HRP-327) - WORKSHEET - Performance Evaluation for IRB Members.

6.8 12.204 (HRP-328) - WORKSHEET - Performance Evaluation Criteria for IRB Staff.

6.9 HRPP Committee Data (Office for Research Data Analytics Dashboards).

6.10 IRB Member Survey Instrument.

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/>.