



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 during the first month of each fiscal year (September).
- 1.3 The process ends when:
 - 1.3.1 All evaluations and assessments have been completed.
 - 1.3.2 The results of the evaluations/assessments have been communicated to the relevant parties via a written report.
 - 1.3.3 The Vice President for Research (VPR), Institutional Official/ Organizational Official (IO/OO), IRB Office Executive Director or designee has confirmed the applicable action items and next steps to address any issues identified.

2 PREVIOUS VERSION

- 2.1 Revised from previous version dated 03/30/2021.

3 POLICY

- 3.1 Northwestern University’s HRPP (for which the IRB Office is at the core) 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 research participant outreach program for enhancing the understanding of participants, prospective participants, and communities is accomplished by making resources pertaining to research participation and the rights of human research participants available to the community on the IRB Office website, partnerships with relevant entities and various outreach activities.

4 RESPONSIBILITIES

- 4.1 IRB Office staff, in conjunction with the Executive Director of the IRB Office, the VPR, and the IO/OO ensure completion of these procedures.

5 PROCEDURE

- 5.1 Have the VPR, IO/OO or designee evaluate the resources (including, but not limited to systems and staffing) 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 Provide an annual report to the IO/OO or designee, outlining the accomplishments, goals, quality improvement activities, workload/performance metrics of the IRBs and IRB Office, including Compliance and Reliance activities, and a summary of any other relevant components of the evaluation process mentioned below.
- 5.4 Have the IO/OO or designee evaluate the HRPP’s emergency preparedness plan and make changes when appropriate.
- 5.5 Evaluate whether the number of IRBs is appropriate to the volume and types of research reviewed.
 - 5.5.1 If applicable, 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.
- 5.6 Use the “WORKSHEET: IRB Composition (HRP-304)” to evaluate whether the composition of the IRB meets regulatory and Institutional requirements.

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



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- 5.6.1 If applicable, work with the IO/OO or designee (such as the IRB Office Executive Director) to modify the IRB composition so that it meets the regulatory and Institutional requirements.
- 5.7 Verify that the IRB registrations have been updated with OHRP within the past year.²
- 5.8 Review “SOP: IRB Formation” (HRP-080) to determine if a new IRB registration is required.
- 5.9 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).
- 5.10 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, scheduled for every 3 years.
 - 5.10.1 If applicable, work with each IRB member to develop a plan to improve the individual’s knowledge, skills, and performance.
 - 5.10.2 Provide each IRB member with a copy of his or her evaluation letter.
- 5.11 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, scheduled for every 3 years.
 - 5.11.1 If applicable, work with each IRB Chair to develop a plan to improve the individual’s knowledge, skills, and performance.
 - 5.11.2 Provide each IRB Chair with a copy of his or her evaluation letter.
- 5.12 Follow the Human Resources annual employee evaluation process to evaluate the knowledge, skills, and performance of IRB Office staff.
 - 5.12.1 Provide each IRB Office staff person with electronic access to his or her annual performance evaluation and if appropriate, work with each IRB Office staff member to develop a plan to improve the individual’s knowledge, skills, and performance.
- 5.13 Have the IRB Office Executive Director or designee evaluate the HRPP education and training program and its resources, to determine if the content is appropriate and impact effective.
- 5.14 Evaluate the participant outreach program.
 - 5.14.1 Consider the following areas when evaluating the outreach plan:
 - 5.14.1.1 Whether the existing scope and content of HRPP outreach materials continue to be adequate;
 - 5.14.1.2 Whether modifications to existing outreach materials are necessary;
 - 5.14.1.3 Whether there are new opportunities to provide outreach activities to the community, and;
 - 5.14.1.4 Whether additional information is needed from the research community to assess the extent to which outreach materials are used and outreach activities take place.
 - 5.14.2 If the participant outreach program is not meeting institutional goals, work with the IRB Office Executive Director or designee to modify the plan. Modifications may include, but are not limited to:
 - 5.14.2.1 Modifying existing outreach materials;
 - 5.14.2.2 Developing new materials;
 - 5.14.2.3 Collaborating with the University human research community and relevant community organizations to identify and participate in additional outreach opportunities.
- 5.15 The Conflict of Interest Office, other units within the Office for Research, the University’s Office of General Counsel and the University’s research affiliates (such as Northwestern Memorial Healthcare, Shirley Ryan Abilitylab and Lurie Children’s Hospital) are separate, independent

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entities from the IRB Office. However, as part of the HRPP program, the IO/OO, IRB Office Executive Director, or designee routinely collaborates with the entities to facilitate discussion and address concerns, which affect the HRPP.

6 MATERIALS

- 6.1 WORKSHEET: IRB Composition (HRP-304)
- 6.2 WORKSHEET: Additional Emergency-Disaster Review Considerations (HRP-352)
- 6.3 SOP: IRB Panel Member 360 Evaluation and Re-Appointment Procedure (HRP-062)
- 6.4 SOP: IRB Formation (HRP-080)
- 6.5 SOP: Emergency Preparedness Plan (HRP-065)
- 6.6 TEMPLATE: IRB Panel Member 360 Survey (HRP-559)

7 REFERENCES

- 7.1 None