1. PURPOSE
   1. This procedure establishes the process to conduct annual evaluations of the human subjects protection program.
   2. The process begins each June.
   3. The process ends when all evaluations have been completed and communicated to those evaluated.
2. REVISIONS FROM PREVIOUS VERSION
   1. None.
3. POLICY
   1. The Human Subjects Protection Program is evaluated annually.
   2. The subject 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 Subjects Protection Program website.
4. RESPONSIBILITIES
   1. IRB staff ensure completion of these procedures.
5. PROCEDURE
   1. Have the HSPP Executive Director or designee evaluate the following resources provided to the Human Subjects Protection Program and adjust as part of the budgeting process.
      1. Space – physical and virtual – and office equipment
      2. HRPP educational program
      3. Availability of legal counsel and/or consultants
      4. Conflicts of interest
      5. Quality assessment and quality improvement activities
      6. Communicate the results of the evaluation to the IO or designee.
   2. Have the HSPP Executive Director or designee evaluate whether the number of IRBs is appropriate to the volume and types of research reviewed.
      1. Communicate the evaluation to the IO or designee.
      2. 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.
   3. Have the HSPP Executive Director or designee annually evaluate the knowledge, skills, and performance of each IRB chair using HRP-326 - WORKSHEET - Performance Evaluation for IRB Chairs and Chair responses to an annual self-assessment survey.
      1. Document and archive a copy of the evaluation and self-assessment in the IRB Member’s Profile in e-IRB.
      2. Communicate the results of the evaluation to each IRB chair and the IO or designee.
      3. If needed, work with each IRB 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.
   4. Have the HSPP Executive Director or designee annually evaluate the knowledge, skills, and performance of each regular and alternate IRB member using HRP-327 - WORKSHEET - Performance Evaluation for IRB Members and IRB member responses to an annual self-assessment survey.
      1. Document and archive a copy of the evaluation and self-assessment in the IRB Member’s Profile in e-IRB.
      2. Communicate the results of the evaluation to each IRB member and the IO or designee.
      3. If needed, work with individual 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.
6. Send a copy of HRP-562 - LETTER - IRB Appreciation to the IRB member’s supervisor.
   1. Have the HSPP Executive Director 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 HRP-328 - WORKSHEET - Performance Evaluation for IRB Staff as part of the evaluation.
      1. Document the results of this evaluation as part of the annual employee evaluation process.
      2. Archive a copy of the evaluation in each IRB staff members personnel file consistent with Rutgers University Human Resources policy.
      3. Provide each IRB staff with a copy of his or her evaluation.
      4. 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.
   2. Use HRP-304 - WORKSHEET - IRB Composition to evaluate whether the composition of the IRB meets regulatory and organizational requirements.
      1. Provide a copy of the evaluation to the IO or designee.
      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.
   3. Have the HSPP Executive Director or designee evaluate the HSPP education program and its resources to determine if the content is appropriate.
   4. Evaluate the subject outreach plan.
      1. Consider the following areas when evaluating the outreach plan:
         1. Whether the existing scope and content of HSPP outreach materials continue to be adequate;
         2. Whether modifications to existing outreach materials are necessary;
         3. Whether or not the HSPP’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;
         4. Whether there are new opportunities to provide outreach activities and/or materials to the community, and;
         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.
      2. Communicate the evaluation to the IO or designee.
      3. If the subject outreach program is not meeting organizational goals, work with the QA Audit Team and IRB Directors/Assistant Directors to modify the plan. Modifications may include, but are not limited to:
         1. Modifying existing outreach materials;
         2. Developing new materials;
         3. Surveying the research community to identify and participate in additional outreach opportunities, and;
         4. Working directly with community organizations to identify and participate in additional outreach opportunities.
   5. Review HRP-080 - SOP - IRB Formation and Registration to determine if IRB registration requires updating.[[1]](#footnote-2)
   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]](#footnote-3)
7. MATERIALS
   1. HRP-080 - SOP - IRB Formation and Registration
   2. HRP-104 - BROCHURE - Should I Take Part in Research
   3. HRP-304 - WORKSHEET - IRB Composition
   4. HRP-326 - WORKSHEET- Performance Evaluation for IRB Chairs
   5. HRP-327 - WORKSHEET - Performance Evaluation for IRB Members
   6. HRP-328 - WORKSHEET - Performance Evaluation Criteria for IRB Staff
   7. HRP-560a, b, & c - LETTERS - IRB Appointment
   8. HRP-562 - LETTER - IRB Appreciation
8. REFERENCES
   1. None.

1. See <http://www.hhs.gov/ohrp/assurances/>. Use the Web site: <http://ohrp.cit.nih.gov/efile/>. [↑](#footnote-ref-2)
2. See <http://www.hhs.gov/ohrp/assurances/>. Use the Web site: <http://ohrp.cit.nih.gov/efile/>. [↑](#footnote-ref-3)