SOP: Annual Evaluations of the HRPP

1. PURPOSE
   1. This procedure establishes the process to conduct annual evaluations of the human research protection program.
   2. The process begins the first business day of each November.
   3. The process ends when all evaluations have been completed and communicated to those evaluated.
2. REVISIONS FROM PREVIOUS VERSION
   1. Clarifications regarding 5.4 and 5.4
   2. Added 3.2.1
3. POLICY
   1. The human research protection program is evaluated annually.
   2. The subject outreach program for enhancing the understanding of subjects, prospective subjects, and communities is accomplished by:
      1. Public facing institutional website for clinical trials: https://www.mountsinai.org/clinical-trials
      2. PPHS website, including a section dedicated to the Public and Research Study Subjects
      3. Making the document HRP-104 - BROCHURE - Should I Take Part in Research available to the patient population.
      4. Various multi-modal ways to share information and teach the research community. For example:
         1. Electronic IRB courses available on Peak
         2. Monthly Clinical Research Forum
         3. Office of Research Services (ORS)
            1. Research Roadmap: Tool to navigate the institutional research infrastructure
            2. Research 411: Support desk for general questions
4. RESPONSIBILITIES
   1. IRB staff ensure completion of these procedures.
5. PROCEDURE
   1. Have the Institutional Official/ Organizational Official (IO/OO) or designee evaluate the following resources provided to the human research protection program and make adjustments as part of the budgeting process. This evaluation will include administrative resources, including:
      1. Space
      2. Personnel
      3. HRPP educational program
      4. Legal counsel
      5. Conflicts of interests
      6. Quality improvement plan
      7. Overall resources to support an AAHRPP-accredited program to ensure accreditation standards can continue to be met
   2. Have the Institutional Official/ Organizational Official (IO/OO) or designee evaluate the HRPP’s emergency preparedness plan and make changes when appropriate.
      1. When updates to the HRPP emergency preparedness plan are made, the IRB Director will designate appropriate IRB staff to make changes to associated educational materials for the HRPP research community.
   3. Evaluate whether the number of IRBs is appropriate to the volume and types of research reviewed.
      1. If the number of IRBs is not appropriate to the volume and types of research reviewed, work with the IO/OO or designee to modify the IRB structure.
   4. Have the Executive Director of the PPHS office ensure that the Dean for Translational and Biomedical Research (Dean) or designee evaluates the knowledge, skills, and performance of each IRB chair using HRP-326 - WORKSHEET - Performance Evaluation for IRB Chairs.
      1. Have the IRB Chairs provide ongoing consultation and peer-feedback to each other.
      2. Ensure all feedback from the Dean is shared with the IRB chairs, as necessary.
      3. Annually, have the IRB member complete the IRB assessment and provide assessment to the IRB chair
      4. If needed, work with each IRB chair to develop a plan to improve the individual’s knowledge, skills, and performance.
      5. Communicate the results of the evaluation to each IRB chair and the IO/OO or designee.
   5. Have the IRB chair evaluate the knowledge, skills, and performance of each regular and alternate IRB member using HRP-327 - WORKSHEET - Performance Evaluation for IRB Members.
      1. Have the IRB chair assess reviewer comments and any attendance issues of board members in advance of each board meeting
      2. Have the IRB chair communicate any concerns identified with the individual IRB member
      3. Annually, have the IRB member complete the IRB member self-assessment
      4. Annually, have the IRB chair meet with the IRB member to discuss evaluation and provide feedback.
      5. If needed, work with the IRB member to develop a plan to improve the individual’s knowledge, skills, and performance.
      6. When a member term is expiring, assess composition and performance of each IRB, and evaluate if member reappointment, reassignment to consultant role, or end of term is appropriate based on attendance, contribution, meeting preparation, and projected needs of the IRB in the coming term. Send a copy of HRP-560A – LETTER – IRB Reappointment.
      7. Have the IRB Chair utilize HRP-327 - WORKSHEET - Performance Evaluation for IRB Members to complete the evaluation. Communicate the results of the evaluation to each IRB member and the IO/OO or designee.
      8. Send a copy of HRP-562 - LETTER - IRB Member Appreciation to the IRB member’s supervisor.
   6. Follow the Human Resources annual employee evaluation process to evaluate the knowledge, skills, and performance of IRB staff. The HRP-328 - WORKSHEET - Performance Evaluation for IRB Staff may be used as part of the evaluation.
      1. Document the results of this evaluation as part of the annual employee evaluation process.
      2. Provide a copy of the evaluation to the IO/OO or designee.
      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.
   7. 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/OO or designee.
      2. If the composition of an IRB does not meet regulatory and organizational requirements, work with the IO/OO or designee to modify the IRB composition.
   8. Evaluate the subject outreach plan.
      1. Consider the following areas when evaluating the outreach plan:
         1. Whether the existing scope and content of HRPP outreach materials, including the PPHS website and the HRP-104 – BROCHURE – Should I Take Part in Research, continue to be adequate;
         2. Whether modifications to existing outreach materials are necessary;
         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;
         4. Whether there are new opportunities to provide outreach activities 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. If the subject outreach program is not meeting organizational goals, work with the IO/OO or designee 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.
   9. Review HRP-080 - SOP - IRB Formation to determine if IRB registration requires updating.[[1]](#endnote-1)
   10. 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]](#endnote-2)
6. MATERIALS
   1. HRP-080 - SOP - IRB Formation
   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 – LETTER – IRB Reappointment
   8. HRP-562 - LETTER - IRB Member Appreciation
7. REFERENCES
   1. AAHRPP elements I.1.A, I-2, I.4.B, II.1.A-D

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