	SOP: Evaluations of the HRPP		
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1 PURPOSE

- 1.1 This SOP establishes the process to conduct annual evaluations of the Human Research Protection Program.
- 1.2 The process begins each fiscal year.
- 1.3 The process ends when all evaluations have been completed and any necessary corrective actions are completed.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Revised from the 5/30/2017 version.

3 SOP Statement


- 3.1 The human research protection program is evaluated on an ongoing basis but no less than annually.
- 3.2 The subject outreach program for enhancing the understanding of subjects, prospective subjects, and communities is accomplished using multiple resources, including the document HRP-104 - BROCHURE - Should I Take Part in Research available to the community population on the HRPP website.

4 RESPONSIBILITY

- 4.1 The Human Research Protection Program Staff ensures the completion of this process.

5 PROCEDURE

- 5.1 Have the Institutional Official or designee evaluate the resources provided to the Human Research Protection Program and make adjustments as part of the budgeting process. Include the following area as applicable:
 - 5.1.1 Space
 - 5.1.2 Personnel
 - 5.1.3 Equipment
 - 5.1.4 Finances
 - 5.1.5 Information Technology Systems
 - 5.1.6 HRPP educational program
 - 5.1.7 Quality Assurance/Improvement Plan
 - 5.1.8 Access to Legal counsel
 - 5.1.9 Conflict of Interest Evaluations
 - 5.1.10 Coordination with Grants and Contracts
- 5.2 Have the Institutional Official (IO) or designee evaluate the HRPP's emergency preparedness plan and make changes when appropriate.
 - 5.2.1 When updates to the HRPP emergency preparedness plan are made, the HRPP Director will designate appropriate IRB staff to make changes to associated educational materials for the HRPP research community.
- 5.3 Evaluate whether the number of IRBs is appropriate to the volume and types of research reviewed.
 - 5.3.1 Communicate results of the evaluation to the IO/QO or designee.
 - 5.3.2 If the number of IRBs is not appropriate to the volume and types of research reviewed, work with the IO/QO or designee to modify the IRB structure.
- 5.4 Have the IRB chair or HRPP Director evaluate the knowledge, skills, and performance of each regular and alternate IRB member using HRP-327 - WORKSHEET - Performance Evaluation for IRB Members.

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- 5.4.1 Have the IRB Chair or HRPP Director 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.
- 5.4.2 If needed, work with each IRB member to develop a plan to improve the individual's knowledge, skills, and performance.
- 5.5 Have the IO/OO or designee evaluate the knowledge, skills, and performance of each IRB chair using HRP-326 - WORKSHEET - Performance Evaluation for IRB Chairs.
 - 5.5.1 Communicate the results of the evaluation to each IRB chair and the IO/OO or designee.
 - 5.5.2 If needed, work with each IRB chair to develop a plan to improve the individual's knowledge, skills, and performance.
 - 5.5.3 Follow the Human Resources annual employee evaluation process to evaluate the knowledge, skills, and performance of HRPP/IRB staff.
- 5.6 Evaluate the subject outreach plan.
 - 5.6.1 Consider the following areas when evaluating the outreach plan:
 - 5.6.1.1 Whether the existing scope and content of HRPP outreach materials continue to be adequate;
 - 5.6.1.2 Whether modifications to existing outreach materials are necessary;
 - 5.6.1.3 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 interaction with the communities in which they conduct research;
 - 5.6.1.4 Whether there are new opportunities to provide outreach activities to the community, and;
 - 5.6.1.5 Whether additional information is needed from the research community to assess the extent to which outreach materials are used and outreach activities take place.
 - 5.6.2 Communicate results of evaluation to the IO/OO or designee.
- 5.7 Evaluate the IRB Composition to ensure it meets the regulatory and institutional requirements.
- 5.8 Review HRP-080 - SOP - IRB Formation and Registration to determine if IRB registration requires updating.¹
- 5.9 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 HRP-080 - SOP - IRB Formation and Registration
- 6.2 HRP-104 - BROCHURE - Should I Take Part in Research
- 6.3 HRP-304 - WORKSHEET - IRB Composition
- 6.4 HRP-326 - WORKSHEET - Performance Evaluation for IRB Chairs
- 6.5 HRP-327 - WORKSHEET - Performance Evaluation for IRB Members
- 6.6 HRP-562 - LETTER - IRB Member Appreciation

7 REFERENCES

- 7.1 21 CFR §56.106 and §56.107
- 7.2 45 CFR §46.107 and 45 CFR §46 Subpart E
- 7.3 AAHRPP I.1.A, 1-2, 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/>.

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