



TITLE: Evaluation of the Human Subjects Protection Program

PURPOSE: Evaluate the Human Subjects Protection Program

RESPONSIBILITIES: HSPP staff

PROCEDURES:

Human Subjects Protection Program

The Organizational Official or designee is responsible for evaluating the resources provided to the Human Subject Protection Program and make adjustments as part of the budget process. The evaluation is ongoing throughout the year, but no less frequent than bi-annually.

1. IRBs

Evaluate whether the number and composition of IRBs are appropriate to the volume and types of research reviewed.

- Provide a copy of the evaluation to the Organizational Official or designee.
- If the number of IRBs is not appropriate to the volume and types of research reviewed, work with the HSPP Director to modify the IRB structure

2. IRB Members

The IRB chair and/or HSPP Director evaluate the knowledge, skills, and performance of each regular and alternate IRB member.

- Provide a copy of the evaluations to the Organizational Official or designee
- Provide each individual IRB member with a copy of their evaluation.
- Send an IRB member appreciation letter copy of the "T652 - IRB Member Appreciation" to the IRB member and others as requested.
- If needed, based on the results of the evaluation, work with IRB member to develop a plan to improve the individual's knowledge, skills, and performance.

3. IRB Chairs

The HSPP Director evaluates the knowledge, skills, and performance of each IRB chair.

- Provide a copy of the evaluation to the Organizational Official or designee.
- Provide each IRB chair with a copy of their evaluation.
- If needed, based on the results of the evaluation, work with the IRB chair to develop a plan to improve the individual's knowledge, skills, and performance.

4. HSPP Staff

HSPP supervisors follow the Human Resources annual employee evaluation process to evaluate the knowledge, skills, and performance of HSPP staff.

- Provide a copy of the evaluation to the Organizational Official or designee.
- Provide each HSPP staff person with a copy of their evaluation.



- If needed, based on the results of the evaluation, work with the HSPP staff person to develop a plan to improve the individual's knowledge, skills, and performance.

5. Subject Outreach Plan

The HSPP Director and IRB Chairs evaluate the subject outreach plan.

- Provide a copy of the evaluation to the Organizational Official or designee
- If the subject outreach plan is not meeting organizational goals, work with the Organizational Official or designee to modify the plan.

6. Maintenance of IRB Registration, Policies, and Processes

- Ensure IRB registration remains valid and is updated or renewed with any necessary information.
- Ensure the Federalwide Assurance (FWA) is updated or renewed.
- Review policies and processes, checklists, templates, worksheets, Investigator's Manual, Operations Manual, HSPP standard operating procedures, and the Human Research Protection Program Plan as needed.

MATERIALS:

- IRB Member Appreciation
- IRB Composition

REFERENCES:

- 45 CFR §46.103, 45 CFR §46.107, 45 CFR 46 Subpart E
- 21 CFR §56.107
- 45 CFR 46, OHRP Frequently Asked Questions (FAQs) on IRB Registrations: <http://www.hhs.gov/ohrp/IRBfaq.html>
- Classified Staff Human Resources Policy 501.0
- University Handbook for Appointed Personnel 5.08

REVIEW/REVISIONS:

From 10/01/10 version: Removed timeline requirements for completion of evaluations

From 2014/01 version: Clarified time frame for completion of evaluation per AAHRPP; Renumbered from P&P-010.