

## SOP: Annual Tasks

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### 1. PURPOSE

- 1.1. This procedure establishes the process to conduct periodic evaluations related to the HRPP.
- 1.2. This procedure will occur at least once yearly.
- 1.3. This procedure ends when evaluations and corrective actions are completed.

### 2. POLICY

- 2.1. The subject outreach program for enhancing the understanding of subjects, prospective subjects, and communities is accomplished by making "BROCHURE: Should I Take Part in Research (HRP-900)" available to the public.

### 3. RESPONSIBILITY

- 3.1. The [Organizational Official] delegates individuals to carry out these procedures.

### 4. PROCEDURE

- 4.1. Evaluate, in consultation with the [IRB Executive Chair] and [HRPP Administrator] as appropriate:
  - 4.1.1. General performance of the HRPP, such as:
    - 4.1.1.1. Feedback from investigators, research staff, sponsors, and subjects
    - 4.1.1.2. Subject outreach plan per SOP: Community Outreach and Engagement.
    - 4.1.1.3. Results of regulatory audits
    - 4.1.1.4. Results of continuous improvement activities
    - 4.1.1.5. New requirements
    - 4.1.1.6. Compliance with policies and procedures
    - 4.1.1.7. Compliance with regulatory requirements
    - 4.1.1.8. Status of action items from previous reviews
  - 4.1.2. HRPP resources for:
    - 4.1.2.1. Space
    - 4.1.2.2. Personnel
    - 4.1.2.3. HRPP educational program
    - 4.1.2.4. Legal counsel
    - 4.1.2.5. Conflicts of interests
    - 4.1.2.6. Quality improvement
  - 4.1.3. Number of IRBs relative to the volume and types of research reviewed
  - 4.1.4. The composition of IRBs relative to "WORKSHEET: IRB Composition (HRP-430)"
  - 4.1.5. Completion of training by IRB members, chairs, vice-chairs, and staff
  - 4.1.6. Evaluate the knowledge and performance of each IRB member, chair, vice-chair, and staff
    - 4.1.6.1. Consult with the [IRB Executive Chair] on the performance of IRB members and staff members.
      - 4.1.6.1.1. Periodicity:
        - 4.1.6.1.1.1. The IRB Chair and Co-Chair and IRB staff will be evaluated yearly.
        - 4.1.6.1.1.2. IRB members will be evaluated one year after an IRB member has been appointed to a committee and two years after that

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- 4.1.6.1.2. Obtain updated résumés or curricula vitae from each IRB member and IRB staff member.
- 4.1.6.1.3. Send the appropriate IRB member the self evaluation.
- 4.1.6.1.4. Member of the IRB will meet with the Chair or Vice Chair and complete a formative evaluation.
- 4.1.6.1.5. Provide each individual with a summary of the individual's evaluation
  
- 4.1.7. Whether IRB members, IRB chairs, IRB vice-chairs, and HRPP staff members have completed required training
- 4.1.8. The effectiveness of the subject outreach plan
- 4.2. A copy of the evaluation will be given to the [Organizational Official].
- 4.3. Take actions as needed to:
  - 4.3.1. Reallocate, add, or modify HRPP resources
  - 4.3.2. Modify the number of IRBs
  - 4.3.3. Modify the composition of IRBs
  - 4.3.4. Remove individuals with persistent knowledge and performance gaps
  - 4.3.5. Correct knowledge and performance gaps of individuals
  - 4.3.6. Arrange for individuals to take missing training
  - 4.3.7. Modify the subject outreach plan
  - 4.3.8. Modify policies and procedures
  - 4.3.9. Provide additional training or modify existing activities, and
- 4.4. Update IRB registrations at <http://ohrp.cit.nih.gov/efile/>.
- 4.5. Update organizational registrations more than four years old at <http://ohrp.cit.nih.gov/efile/FwaRenew.aspx>.

## 5. REFERENCES

- 5.1. 21 CFR §56.106 and §56.107
- 5.2. 45 CFR §46.107 and 45 CFR §46 Subpart E