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1. PURPOSE

- 1.1. This procedure establishes the process to conduct annual tasks related to the HRPP.
- 1.2. This procedure begins every year in May.
- 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 subject information available on the [Organization's] Web site.

3. RESPONSIBILITY

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

4. PROCEDURE

- 4.1. Obtain updated résumés or curricula vitae from each IRB member and HRPP staff member (or confirmation that the existing one is still accurate).
- 4.2. Evaluate in consultation with the [IRB Executive Chair] and [HRPP Administrator] as appropriate:
 - 4.2.1. General performance of the HRPP, such as:
 - 4.2.1.1. Feedback from investigators, research staff, sponsors, and subjects
 - 4.2.1.2. The subject outreach plan
 - 4.2.1.3. Results of regulatory audits
 - 4.2.1.4. Results of continuous improvement activities
 - 4.2.1.5. New requirements
 - 4.2.1.6. Compliance with policies and procedures
 - 4.2.1.7. Compliance with regulatory requirements
 - 4.2.1.8. Status of action items from previous reviews
 - 4.2.2. HRPP resources for:
 - 4.2.2.1. Space
 - 4.2.2.2. Personnel
 - 4.2.2.3. HRPP educational program
 - 4.2.2.4. Legal counsel
 - 4.2.2.5. Conflicts of interests
 - 4.2.2.6. Quality improvement
 - 4.2.3. Whether the number of IRBs is appropriate to the volume and types of research reviewed
 - 4.2.4. Whether the composition of IRBs meets the requirements in "WORKSHEET: IRB Composition (HRP-430)"
 - 4.2.5. Whether the IRB and organizational registrations have been updated in the past two years
 - 4.2.6. The knowledge and performance of each IRB member, IRB chair, IRB vice-chair, and HRPP staff member
 - 4.2.6.1. Consult with the [IRB Executive Chair] on the performance of IRB members and HRPP staff members.
 - 4.2.7. Whether IRB members, IRB chairs, IRB vice-chairs, and HRPP staff members have completed required training
 - 4.2.8. The effectiveness of the subject outreach plan
- 4.3. Provide a copy of the evaluation to the [Organizational Official].

SOP: Annual Tasks

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- 4.4. Take actions as needed to:
 - 4.4.1. Reallocate, add, or modify HRPP resources
 - 4.4.2. Modify the number of IRBs
 - 4.4.3. Modify the composition of IRBs
 - 4.4.4. Remove individuals with persistent knowledge and performance gaps
 - 4.4.5. Correct knowledge and performance gaps of individuals
 - 4.4.6. Arrange for individuals to take missing training
 - 4.4.7. Modify the subject outreach plan
- 4.5. Provide each individual with a summary of the individual's evaluation
- 4.6. If a member is recommended for reappointment, send letter thanking them for their service, inviting them to accept reappointment for the year, and offering them an opportunity to obtain feedback on their performance for the previous year.
- 4.7. Update IRB registrations at <http://ohrp.cit.nih.gov/efile/>.
- 4.8. 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