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 January.
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. The subject outreach plan
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. HRPP educational program
4.1.2.3. Legal counsel
4.1.2.4. Conflicts of interests
4.1.2.5. 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. 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 HRPP staff members.
4.1.7. Whether IRB members, IRB chairs, IRB vice-chairs, and HRPP staff members have completed required training

4.2. Communicate the evaluation 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. The [HRPP Administrator] ensures completion of the following administrative tasks:

4.4.1. Identify IRB members whose terms expire in the coming year. Determine whether these individuals will be reappointed or removed. Follow “HRP-132 SOP – IRB Member Appointment” or “HRP-133 – IRB Member Removal” as applicable.

4.4.2. Send a thank you letter to each IRB member, IRB chair, and IRB vice-chair and if applicable, copy the individual’s supervisor.


4.4.4. Update organizational registrations more than four years old at http://ohrp.cit.nih.gov/efile/FwaRenew.aspx.

4.4.5. Conduct an audit to discover and resolve expired Exempt studies.


5. REFERENCES

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