



SOP: Annual Tasks

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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 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



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- 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.
 - 4.4.3. Update IRB registrations at <http://ohrp.cit.nih.gov/efile/>.
 - 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.
 - 4.4.6. Update Oregon State IRB registration (see <http://public.health.oregon.gov/diseasesconditions/geneticconditions/pages/research.aspx>).

5. REFERENCES

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