

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 July.
- 1.3. This procedure ends when evaluations and corrective actions are completed.

2. POLICY

- 2.1. None

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.
- 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 Subject outreach plan per SOP: Community Outreach and Engagement.
 - 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 HRPP educational program
 - 4.2.2.3 Legal counsel
 - 4.2.2.4 Conflicts of interests
 - 4.2.2.5 Quality improvement
 - 4.2.3. Number of IRBs relative to the volume and types of research reviewed
 - 4.2.4. The composition of IRBs
 - 4.2.5. Completion of training by IRB members, chairs, vice-chairs, and staff
 - 4.2.6. The knowledge and performance of each IRB member, chair, vice-chair, and staff
 - 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].
- 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

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4.4.7. Modify policies and procedures

4.4.8. Provide additional training or modify existing activities, and

4.5. Provide each individual with a summary of the individual's evaluation

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

5. REFERENCES

5.1. 21 CFR §56.106 and §56.107

5.2. 45 CFR §46.107 and 45 CFR §46 Subpart E