



SOP: Annual Tasks

Document No.:	Edition No.:	Effective Date:	Page:
HRP-141	001	18 DEC 2018dd MMM YYYY	Page 1 of 2

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. Membership and composition of the IRB is evaluated periodically to ensure quality of review is maintained.
- 2.2. IRB registration and federalwide assurance is updated/renewed as required by OHRP.

3. RESPONSIBILITY

- 3.1. The Institutional 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 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. Results of regulatory audits
 - 4.2.1.3. Results of continuous improvement activities
 - 4.2.1.4. New requirements
 - 4.2.1.5. Compliance with policies and procedures
 - 4.2.1.6. Compliance with regulatory requirements
 - 4.2.1.7. 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 composition of the IRB meets the requirements in "WORKSHEET: IRB Composition (HRP-430)"
 - 4.2.4. The knowledge and performance of each IRB member, IRB chair, and HRPP staff member
 - 4.2.5. Whether IRB members, IRB chairs, and HRPP staff members have completed required training
- 4.3. Provide a copy of the evaluation to the Institutional Official.
- 4.4. Take actions as needed to:
 - 4.4.1. Reallocate HRPP resources
 - 4.4.2. Modify the composition of IRB
 - 4.4.3. Remove individuals with persistent knowledge and performance gaps
 - 4.4.4. Correct knowledge and performance gaps of individuals
 - 4.4.5. Arrange for individuals to take missing training
- 4.5. Update IRB registration prior to 3-year expiration at <http://ohrp.cit.nih.gov/efile/>.
- 4.6. Update institutional registration prior to 5-year expiration at <http://ohrp.cit.nih.gov/efile/FwaRenew.aspx>.



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Document No.:	Edition No.:	Effective Date:	Page:
HRP-141	001	18 DEC 2018dd MMM YYYY	Page 2 of 2

5. REFERENCES

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