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
5. REFERENCES

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