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1. PURPOSE

- 1.1. This procedure establishes the process to conduct annual evaluations of the human research protection program,
- 1.2. This procedure begins every year in July.
- 1.3. This procedure ends when evaluations have been complete and communicated to the entities evaluated.

2. POLICY

- 2.1. The human research protection program is evaluated annually.
- 2.2. The subject outreach program for enhancing the understanding of subjects, prospective subjects, and communities is accomplished using multiple resources, including the clinic-based research [Brochure "Should I Take Part in Research \(HRP – 900\)](#), information provided on the Office of Research’s HRPP website, and prospective participant outreach initiatives through the various UF CTSI’s Community engagement programs and other programs at the University of Florida.

3. RESPONSIBILITY

- 3.1. The Institutional Official delegates individuals to carry out these procedures.

4. PROCEDURE

- 4.1. Evaluate in consultation with those responsible for implementing the HRPP:
 - 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
 - 4.1.2. HRPP resources for:
 - 4.1.2.1. Space
 - 4.1.2.2. Personnel
 - 4.1.2.3. HRPP educational program
 - 4.1.2.4. Legal counsel
 - 4.1.2.5. Conflicts of interests
 - 4.1.2.6. Quality improvement
 - 4.1.3. Turnaround times for Full Board and Non-Full Board reviews
 - 4.1.3.1. Track results in consultation with the Director of Research Operations and Services
 - 4.1.3.2. Examine significant trends
 - 4.1.3.3. Generate report of all relevant metrics data required for annual AAHRPP Accreditation Reporting.
 - 4.1.4. Number of IRBs relative to the volume and types of research reviewed
 - 4.1.5. The composition of IRBs relative to ["IRB REGULATORY GUIDANCE: IRB Composition \(HRP-430\)"](#)

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- 4.1.6. Training and evaluation of IRB members, chairs, and vice-chairs
 - 4.1.6.1. New member orientation and training includes:
 - 4.1.6.1.1. A review of the Belmont Report, 45 CFR 46, Chapter 3 of the OHRP Guidebook, OHRP’s Informed Consent Tips, UF’s FWA, NIH Board Member training, and a review of UF IRB’s Policies and guidance’s.
 - 4.1.6.1.2. IRB Investigator training (CITI modules) and HIPAA Privacy training.
 - 4.1.6.1.3. Review and training of the myIRB electronic IRB submission and review software
 - 4.1.6.1.4. Two face-to-face training meetings with the IRB Educator.
 - 4.1.6.1.5. Must attend two Full Board meetings with a current IRB member that serves as a mentor
 - 4.1.6.1.6. An individual meeting with the IRB chair.
 - 4.1.6.2. Continuing education of IRB members shall be conducted periodically by the IRB Education Coordinator and the IRB Chairs. The continuing education will include updates on regulatory and review process topics during IRB meetings and monthly at Brown Bag lunches, and a monthly copy of the “Human Research Report.” The IRB will convene a retreat annually for IRB members and office staff as part of the continuing education.
 - 4.1.6.3. Educational requirements for IRB members are monitored by the IRB Education Coordinator. IRB members who have not completed their training cannot engage in their specific responsibilities until requirements have been met.
 - 4.1.6.4. Periodic assessment and feedback will be provided to IRB members, IRB chairs, and vice-chairs when appropriate.
 - 4.1.6.5. IRB members are appointed for 3-yr terms that may be renewed indefinitely.
 - 4.1.6.6. The Organization will periodically conduct a self-assessment of IRB chairs and members. UF IRB chairs will be asked to evaluate vice-chairs and members, and the IRB members will be asked to evaluate chairs. This evaluation will use a form developed by the IRB.
 - 4.1.6.7. The completed forms will be submitted to the Director of Research Operations and Services for review and to the Board member’s non-IRB supervisor, and will be considered as part of the IRB committee membership and leadership appointment process.
- 4.1.7. Training and evaluation of IRB staff:
 - 4.1.7.1. IRB staff must complete initial training as appropriate for their job duties. The training is documented on the orientation checklist and must be completed as needed before assuming specific duties. In addition to local job specific training (e.g. how to use the database), staff must also complete the following initial training: CITI, HIPAA (for any IRB approving research that involves PHI), local IRB training, read the Belmont Report, and read the IRB Policies and Procedures. All initial training is documented on the "Orientation Checklist"
 - 4.1.7.2. As part of the continuing education requirements, IRB staff shall complete the annual HIPAA for Researchers training, and receive on-going training at twice monthly staff meetings, IRB Brown Bag

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Seminars, attending annual IRB retreat, and attendance at PRIM&R (for select number of staff each year).

- 4.1.7.3. Educational and training requirements for IRB staff are monitored by the assigned supervisor of each office. IRB staff who have not completed their training cannot engage in their specific responsibilities until requirements have been met.

4.2. Take actions as needed to:

- 4.2.1. Reallocate, add, or modify HRPP resources
- 4.2.2. Modify the number of IRBs
- 4.2.3. Modify the composition of IRBs
- 4.2.4. Remove individuals with persistent education/training, knowledge, and performance gaps
- 4.2.5. Correct knowledge and performance gaps of individuals
- 4.2.6. Arrange for individuals to take missing training
- 4.2.7. Modify the subject outreach plan
- 4.2.8. Modify policies and procedures
- 4.2.9. Provide additional training or modify existing activities, and

4.3. If needed, update IRB registrations at <http://ohrp.cit.nih.gov/efile/>.

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

5. REFERENCES

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