1. **PURPOSE**

1.1. This policy establishes the process to conduct quality improvement of the human research protection program (HRPP).

2. **POLICY**

2.1. The goal of the HRPP quality improvement plan is to assess, improve, document, and report the compliance, quality, effectiveness, and efficiency of the HRPP.

3. **Responsibilities**

3.1. The HRPP Administrator is responsible for ensuring that this policy is implemented.

3.2. Unit specific HRPP staff carry out quality improvement (QI) activities.

3.3. The HRPP Administrator works with applicable HRPP component units to implement improvements.

4. **PROCEDURE**

4.1. Compliance Activities

4.1.1. IRB Minutes

4.1.1.1. **Goals:**

4.1.1.1.1. Ensure that IRB minutes comply with regulatory requirements.

4.1.1.1.2. Ensure that minutes are completed in a timely fashion.

4.1.1.1.3. Identify areas for improvement.

4.1.1.1.4. Identify if corrective action is required.

4.1.1.2. Process to make improvements:

4.1.1.2.1. IRB QA team to audit at least two full board meeting meetings for each UF IRB each calendar year.

4.1.1.2.2. IRB Assistant Director will assess, consult IRB Chairs if appropriate, and determine if changes need to be implemented or corrective action taken (e.g. train staff, correct past minutes, etc.).

4.1.1.2.3. Assessment (including any changes or corrective action) will be documented and reported (a) semiannually to IRB Chairs, IRB Assistant Director, HRPP Administrator, and IRB QI team to assess effectiveness in next audit of minutes; (b) annually to the Institutional Official (IO) in the Annual HRPP Evaluation.

4.1.2. IRB Post Audit Surveys

4.1.2.1. **Goals:**

4.1.2.1.1. Improve investigator compliance.

4.1.2.1.2. Assess investigator knowledge of regulatory requirements.

4.1.2.1.3. Assess any correlations between survey results and audit findings.

4.1.2.1.4. Identify if corrective actions are required with (a) specific investigators based on responses, and (b) for HRPP (e.g. training initiatives needed, systematic improvements, etc.).

4.1.2.2. Process to make improvements:
4.1.2.2.1. IRB QA to solicit an Investigator Post-Audit Survey after every Random QA Audit.

4.1.2.2.2. IRB Assistant Director will assess, consult IRB Chairs if appropriate, and determine if changes need to be implemented or corrective action taken (e.g. implement new training initiatives, identify issue for assessment in Post Approval Monitoring, etc.).

4.1.2.2.3. Assessment (including any changes or corrective action) will be documented and reported (a) semiannually to IRB Chairs, IRB Assistant Director, and HRPP Administrator; (b) annually to the IO in the Annual HRPP Evaluation.

4.2. Quality, efficiency, and effectiveness goals

4.2.1. IRB Post Approval Surveys

4.2.1.1. Goals:

4.2.1.1.1. Assess the quality, efficiency, and effectiveness of IRB review and approval of new research protocols.

4.2.1.1.2. Obtain feedback from researchers about IRB staff, IRB reviewers, myIRB, and timeliness of IRB review.

4.2.1.1.3. Assess feedback in real time to (a) address any immediate issues or complaints, and (b) share compliments with staff and reviewers.

4.2.1.1.4. Assess aggregated feedback semiannually to identify and address any trends or systematic areas that need improvement.

4.2.1.2. Process to make improvements:

4.2.1.2.1. Solicit feedback from researchers about their experience obtaining IRB approval. myIRB automatically sends an email with a link to a Qualtrics survey after the approval of every new study.

4.2.1.2.2. IRB Assistant Director will review post-approval surveys in real time to address any immediate issues/concerns. If applicable, IRB Chairs and HRPP Administrator will be consulted.

4.2.1.2.3. Results will be aggregated semi-annually and assessed by the IRB Chairs, IRB Assistant Director, and HRPP Administrator.

4.2.1.2.4. Assessment, issues, and any corrective actions will be documented and reported to the IO in the annual HRPP Evaluation.

4.2.2. IRB Metrics

4.2.2.1. Goal:

4.2.2.1.1. For each UF IRB, assess work volume, turnaround time, and other metrics as needed.

4.2.2.1.2. Assess if resources are appropriate to ensure mission to protect subjects.

4.2.2.1.3. Identify if process improvements, resource allocation, or other measures are needed.

4.2.2.2. Process to make improvements:
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4.2.2.2.1. IRB metrics will be formally evaluated semiannually by the IRB Chairs, IRB Assistant Director, and HRPP Administrator.

4.2.2.2.2. Assessment, issues, and any corrective actions will be documented and reported to the IO in the annual HRPP Evaluation.

4.3. Ad hoc (a) compliance goals, and (b) quality, efficiency, and effectiveness goals

4.3.1. All HRPP component units (IRB chairs and IRB administration, COI, Contracts, Community Outreach, Legal Counsel, etc.) will be asked semi-annually to assess their units and determine if any HRPP Quality Improvement Plans were or should be pursued in that unit.

4.3.1.1. Goals:

4.3.1.1.1. Review overall status of the HRPP semiannually.
4.3.1.1.2. Assess if improvements are needed or possible.
4.3.1.1.3. Assess if there are any areas of concern.
4.3.1.1.4. Monitor status of previously implemented QI plans.

4.3.1.2. Process:

4.3.1.2.1. HRPP Coordinator will contact HRPP components units quarterly to (a) assess if new ad hoc quality improvement plans are being considered or implemented, and (b) to report the status or results of any existing plans.

4.3.1.2.2. Representatives from the HRPP component units will meet semiannually to review the overall status of the HRPP as well as any active QI initiatives.

4.3.1.2.3. Assessment, issues, and any corrective actions will be documented and reported to the IO in the annual HRPP Evaluation.

5. REFERENCES

5.1. AAHRPP Element 1.5.A
5.2. AAHRPP Element 1.5.B
5.3. IRB QA Audit Summary Checklist
5.4. Investigator Post Audit Survey
5.5. Investigator Post Approval Survey
5.6. HRPP Semiannual Quality Improvement Report