Quarterly Evaluations of the HRPP

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1. PURPOSE

1.1. This document establishes the ***policy*** and procedures for conducting quality improvement of the Human Research Protections Program (HRPP) at the University of Georgia (UGA).

2. DEFINITIONS

2.1. ***Quality Improvement Program (QIP)***: The systematic and continuous actions that lead to measurable improvement in the Human Research Protections Program.

3. POLICY

3.1. The goal of the quality improvement program is to achieve and maintain compliance with the applicable federal, state, and institutional regulations and policies for the protections of ***human research participants*** and to achieve targeted levels of quality, efficiency, and effectiveness of the HRPP.

3.2. The objectives of the HRPP quality improvement program are to:

3.2.1. Improve compliance of ***investigators*** with their responsibilities.

3.2.2. Improve compliance of minutes with regulatory requirements.

3.2.3. Increase efficiency of recording and finalizing minutes.

3.3. The measures of the quality improvement program are defined in:

3.3.1. CHECKLIST: Investigator Quality Improvement Assessment

3.3.2. CHECKLIST: Minutes Quality Improvement Assessment

4. PROCEDURES: IRB Staff

4.1. The Designated IRB Staff will randomly identify 10% of approved studies that are ***federally funded*** every quarter. The Designated IRB Staff must complete *TEMPLATE LETTER: Investigator Quality Improvement Assessment* and send *CHECKLIST: Investigator Quality Improvement Assessment* to investigators of the studies identified for assessment.

4.2. The Designated IRB Staff must review the results of *CHECKLIST: Investigator Quality Improvement Assessment* sent out the previous quarter, track the results, and examine them for significant trends.

4.3. The Designated IRB Staff must complete the *CHECKLIST: Minutes Quality Improvement Assessment* on the minutes of the previous quarter, and track compliance and the days required to complete minutes, and examine them for significant trends.

4.4. The Designated IRB Staff must send the results to the Human Subjects Office (HSO) Director.

4.5. If the results of any evaluations demonstrate high variability or are outside performance targets, the Designated IRB Staff must work with the Institutional Official or Designee, the

Office of Research Compliance Director, the IRB Chair, and/or HSO Director to implement an intervention.

5. **MATERIALS**
   - 5.1. CHECKLIST: Investigator Quality Improvement Assessment
   - 5.2. CHECKLIST: Minutes Quality Improvement Assessment
   - 5.3. TEMPLATE LETTER: Investigator Quality Improvement Assessment

6. REFERENCES
   - 6.1. None