UNIVERSITY OF GEORGIA
Human Research Protection Program

Quarterly Evaluations of the HRPP

Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-061-1	05/27/2021	HSO	HSO Director (HRPP Policy Committee notified)	Page **1** of **3**

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.

3.2.4. Increase compliance of protocol reviews with regulatory requirements.

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

3.3.3. WORKSHEET: QA/QI Non-Exempt Initial Reviews

3.3.4. CHECKLIST: QA/QI Monthly Review Audit

3.3.5. HRPP Satisfaction Survey

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 HRPP Satisfaction Survey is made publicly available on the HRPP website and a link to the online survey is provided in all portal submission notifications.

4.3. 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.

4.4. The Designated IRB Staff must complete the *CHECKLIST: QA/QI Meeting Minutes Assessment* on the minutes of the previous quarter, and track compliance and the days required to complete minutes, and examine them for significant trends.

4.5. Prior to finalizing approval of non-exempt Human Research, the Designated IRB Staff will use WORKSHEET: QA/QI Non-Exempt Initial Reviews to ensure review documentation is adequate and in compliance with regulatory requirements.

4.5.1. The Designated IRB Staff will use Daily Log for Non-Exempt Initial Submissions QA/QI to track findings and examine for significant trends to identify training needs.

4.5.2. The Designated IRB Staff must send the results to the Human Subjects Office (HSO) Director each quarter and provide a summary of trends at a regularly scheduled staff meeting.

4.6. Each month, the Designated IRB Staff will obtain a report of all federally-funded submissions approved in the prior 30 days.

4.6.1. The Designated IRB Staff will use CHECKLIST: QA/QI Monthly Review Audit as a guide to audit reviews for compliance with regulatory requirements and UGA Policies.

4.6.2. The Designated IRB Staff must send results to the Human Subjects Office (HSO) Director each quarter and provide training as needed using QA/QI Quarterly Review of Monthly Review Audits to document training.

4.7. If the results of any evaluations demonstrate high variability or are outside performance targets, the Designated IRB Staff will work with the Institutional Official or Designee, the Office of Research Integrity and Safety Director, the IRB Chairs, and/or HSO Director to implement an intervention.

5. **MATERIALS**

5.1. CHECKLIST: Investigator Quality Improvement Assessment

5.2. CHECKLIST: QA/QI Meeting Minutest

5.3. TEMPLATE LETTER: Investigator Quality Improvement Assessment

5.4. WORKSHEET: QA/QI Non-Exempt Initial Reviews

5.5. Daily Log for Non-Exempt Initial Submissions QA/QI

5.6. CHECKLIST: QA/QI Monthly Review Audit

5.7. QA/QI Quarterly Review of Monthly Review Audits

Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-061-1	05/27/2021	HSO	HSO Director (HRPP Policy Committee notified)	Page **3** of **3**

6. REFERENCES

6.1. None

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05/27/2021: REV1