1. PURPOSE

1.1. This procedure establishes the Quality Assurance Program.

1.1.1. This program was created to assess the research activities conducted under and in accordance with the University’s Federal Wide Assurance Agreement with the Office of Human Research Protections (OHRP), DHHS.

1.1.2. The Quality Assurance (QA) component of the University of Florida Institutional Review Boards evaluates the current practices of the IRB and University of Florida Research community against the defined standards, of the DHHS (including OHRP), FDA, State of Florida, University of Florida, and the IRB Policies.

2. POLICY

2.1. This program conducts random and for cause evaluations of research conducted by UF faculty and staff, regardless of the IRB oversight, to ensure adherence with federal regulations, state and local laws, and institutional policies and procedures governing the UF Human Research Protections (HRPP) Program.

2.1.1. Any human subjects’ research under any UF IRB may be subject to for cause or random audits

2.1.1.1. For cause audits may occur as a result of known or suspected non-compliance in the conduct of human subject research reported to or identified by the Board, Executive Committee, or Administrative Office.

2.1.1.2. Projects identified for random audits will be based on the following criteria:

- Federal or internally funded projects
- Projects that are actively enrolling subjects
- Projects that have local or no oversight
- Studies involving gene therapy
- Studies involving human subject volunteers
- Studies that are minimum to high risk
- New investigators, investigators with multiple open research protocols
- Other criteria that the QA Coordinator deems appropriate

2.2. In addition, the QA Program provides training and education to researchers and their study teams and provides them with tools to facilitate the conduct of their research.

2.2.1. Investigator and/or study teams may request audits of their studies at start-up or anytime deemed appropriate by the study team.

2.2.1.1. Provide QA review prior to taking over as PI for a previously approved study

2.2.1.2. Provide assistance with preparation for an external audit

2.2.1.3. Assist with creating study team tools to facilitate documentation of research activities

2.2.1.4. Small group in-service QA/QI training sessions

3. RESPONSIBILITY

3.1. Quality Assurance Coordinators carry out these procedures under the direction of the Assistant Director of the IRBs.

4. PROCEDURE
4.1. For cause audits may be referred to the UF QA Program by the Board, Executive Committee, or Administrative Office via phone, e-mail, or letter. Pertinent information will be obtained from the requesting source. The Principal Investigator will be notified of the audit via letter delivered through UF campus mail and copied by e-mail, and/or by phone that a for cause audit is warranted and a mutually convenient time for the audit will be scheduled.

4.1.1. Once the audit has been completed, the QA Coordinator will summarize the findings in a report which will be sent to the Assistant Director of IRBs and appropriate IRB Chair. If there are findings of serious non-compliance, the IRB Chair may take immediate action and it will be up to the Board/IRB Chair to determine how the PI will be notified of the findings.

4.1.2. The Audit Summary will be added to an agenda to discuss at the earliest possible convened meeting where the corrective action will be determined by the Chair and Board members.

4.1.3. The Audit Report becomes part of the IRB files for the research project.

4.2. After a project is identified for a random audit, the Principal Investigator is be notified in writing via letter delivered through UF campus mail and copied by e-mail. Once notified, the audit is scheduled at a mutually convenient time within 6 weeks of notification.

4.2.1. Once the audit has been completed, the QA Coordinator will provide the PI a written report summarizing findings, requesting action and/or providing recommendations. Any findings of non-compliance will be handled per the IRB Noncompliance Policy.

4.2.1.1. In addition to the written audit report, the QA Coordinator will also request that the PI complete the “Investigator Post-Audit Survey” as per policy “IRB Quality Improvement Evaluations” (HRP-142).

4.2.2. Results of random audits will be maintained in separate QA Files, and not with the IRB Project File, unless referred for review to the Chair or Board.

4.3. Prior to for cause or random audits, the corresponding IRB file, including initial submission (IQ, protocol, IC, advertisements, etc), project approvals (including IC), revisions to protocol, reporting of AEs/SAEs, continuing review documents and any additional documentation included in the IRB file will be reviewed for appropriate records.

4.4. Audits of VA Research will be conducted in conjunction with the NF/SG VHS Research Compliance Officer and findings communicated in writing.

4.4.1. Any findings of IRB noncompliance will be handled per VA 1200.05.

4.5. As part of for cause or random audits, the informed consent process may be monitored, as needed, by the QA Coordinator or an experienced designee.

4.6. Audits provide Research Teams an opportunity to learn through external evaluation.

4.6.1. During the audit process, the QA Coordinator can assess the study staff’s knowledge and training needs regarding compliance with local and federal regulations as well as GCP guidelines. In addition to on-site discussions and training related to the audit, the QA Coordinator may also direct the research team to additional training opportunities.

5. REFERENCES

5.1. 21 CFR §56.109(f)