Auditing Research Studies

January 2017

Background:
The Office of Research and Graduate Programs (RGP) at the University of Florida is committed to improving the quality and integrity of its research programs, and to enhancing the protection of human subjects participating in those programs. In pursuit of this commitment, the RGP has created a Quality Assurance (QA) Program to assess the research activities conducted in accordance with the University’s Assurance Agreement with the Office of Human Research Protections, DHHS.

Part of the UF Quality Assurance/Quality Improvement Program aims to assist the University of Florida and the researchers in performing human subjects research within the framework of State and Federal regulations, institutional policies, and good clinical practice through on-going monitoring of UF IRB approved studies.

Q: How can the QA/QI Program benefit you?

- **Random on-site reviews**
  - On-site reviews initiated by the QA/QI program. The investigator is notified by email/letter and a date is arranged that fits the investigator/research staff schedule. These audits typically take 4 to 6 hours to complete, but may exceed this time period if necessary.
  - Typically the outcome of the random audits are not shared with the IRB if only minor deficiencies in Human Research Protections are found and reporting methods are worked out between the QA/QI staff member and investigator/research team. Minor deficiencies are those activities that do not impact subject safety, do not pose risks to subjects, or do not affect data integrity. If the investigator does not report the minor deficiencies or take corrective action as specified in the audit summary report, the QA/QI staff member is obligated to report this information to the IRB.
  - Random monitoring findings that result in significant or serious deficiencies that place subjects at risk or can affect data integrity will require the QA/QI staff member to report the findings immediately to the IRB Chair.

- **For cause on-site reviews**
  - For Cause reviews are initiated at the request of IRB Chair, the assistant director for research, or by the Board due to allegations or concerns about the conduct of the study which have been brought to the IRBs attention, submission paperwork which is inconsistent with what the IRB had approved, or deviations or adverse event reporting that may present
significant risks to subjects, and/or routine failure of the investigator to comply with federal and/or institutional requirements.

- These audits include full review of the regulatory files and all subject files and may require two QA/QI staff members to complete. These audits may take up to 6 hours or greater than one day to complete and the summary report will be shared with the IRB.

- Investigator requested reviews
  - Prior to taking over as PI for a previously approved study, at study start-up, or anytime deemed appropriate by the Investigator/study team, an on-site review may be requested.
  - This review may include a full audit of the regulatory files and all subject files, general study consultation for study to ask specific questions related to their protocol, regulatory binder/study subject research chart consultation, and/or assistance in creating study team tools to facilitate documentation of research activities.

- Educational in-services
  - At the request of the investigator and/or study staff. This service provides the study team with an opportunity to ask questions, discuss policies and address specific issues relating to the conduct of the research.

- Assistance with preparation for FDA/NIH audit

**Q: How do I request QA/QI Program Services?**

You may send your request to our listserv, ufirb-l@lists.ufl.edu, or contact the IRB Office at 352-273-9600 and ask to speak to one of our QA/QI Coordinators.

**Q. What should I do if I suspect research noncompliance?**

Noncompliance with ethical standards, federal regulations, other laws, or institutional polices must be reported to the IRB.

You will not be harassed, discriminated against, or be subject to any reprisals or retaliations for reporting violations in good faith. You may provide the information anonymously. If you choose to reveal your identity, you will be protected to the extent possible by law.

To report noncompliance or misconduct contact:

- Anonymously: 1-877-556-5356 or go to reportlineweb.com/uf
- IRB Compliance Hotline at (352) 294-5549

For more information about reporting concerns involving human subjects research see Concerns or Complaints About Research Guideline [Link to document].
Researchers should self-report noncompliance by submitting the appropriate paperwork to the IRB of record for the research, Deviation/Noncompliance Reporting Forms can be found on the following webpage: http://irb.ufl.edu/index/noncompliance.html.