



College of Pharmacy Regulatory and Compliance Support Office

Mission: To support investigators in the College of Pharmacy with the federal, state and institutional regulatory and compliance requirements.

Support Provided:

- All new and clinical track faculty are provided cradle to grave regulatory and compliance support for their first IRB submission. This includes transfer of study samples and data to UF, new protocol submission, RAC review, and clinical trials registration, as well as ongoing, continuing review, and study closure assistance. Provide new faculty with all the forms, deadlines, and offices that need to be included for a study at UF.
- All existing research-intensive (tenure track) faculty members are provided consultative support on all regulatory and compliance matters. This office will review provide guidance on the forms that are needed for a specific protocol submission documents, provide insight into new forms needed on continuing review, review all IRB documents prior to submission, answer questions, and meet with faculty members. Attendance at local IRB meetings when requested by local investigators.
- Assist PIs by reviewing submissions for data use, material use, and other transfer agreements.
- Assist in the training of students/trainees in regulatory requirement of human subject use in research. Meet with students to help them understand their responsibilities and their mentor's role in their proposed research. Advise them where to find forms and offer to review their documents after their mentor has reviewed and approved their work.
- Review academic honors research projects involving human subjects research and advise regarding UF policy. Route to the IRB if needed.
- Update/maintain SSC website and produce content for the website.
- Provide local training seminars and attend online, local, and national meetings and conferences.
- Serve as an intermediary for communication between College of Pharmacy researchers and the institutional and federal governing bodies.
- Assist and advocate for researchers within the College of Pharmacy when they are under review or audit.

This office *cannot* act as a research coordinator to provide daily/weekly hands-on support to manage a PI's research program or database. The office will not be responsible for obtaining informed consent, updating EPIC records, processing or recording payments, or monitoring of protocol compliance or deviations. PI must be the responsible party for all IRB submissions, therefore all submissions must be approved by the PI.