January 2024 Edition

USF IRB Newsletter

Your source for updates from the University of South Florida Institutional Review Board

Individual Investigator Agreement (IIA)

USF IRB wants Investigators and Study Team Members to know what an Individual Investigator Agreement (IIA) is and when it can be used. As described in section 41 of the USF HRP-103 Investigator Manual an IIA is a written agreement between the USF IRB and the independent Investigator who is collaborating on USF research. This is where USF is agreeing to extend its oversight to the individual, and by which the independent Investigator agrees to fulfill specified expectations and responsibilities. Currently the USF IRB is only agreeing to IIAs for federally funded research. If the IIA is applicable for you, there are two separate types of independent investigators:

1) Collaborating **Independent Investigator** who, is not otherwise an employee or agent of the assured Institution (USF); conducting collaborative research activities outside the facilities of the assured Institution (USF); and not acting as an employee of any institution with respect to his or her involvement in the research being conducted by the assured institution.

2) Collaborating **Institutional Investigator** who, is not otherwise an employee or agent of the assured Institution (USF); conducting collaborative research activities outside the facilities of the assured Institution (USF); acting as an employee or agent of a non-assured institution with respect to his or her involvement in the research being conducted by the assured Institution (USF); and employed by, or acting as an agent of, a non-assured institution that does not routinely conduct human subjects research.

Review these tips and tricks when completing the BullsIRB application for an IIA

- IIAs may be included in an initial application **or** in a modification application.
- Investigators should reach out to the Reliance Office to see if the IIA form is appropriate for their research and to make sure that all required information is collected from the individuals who may use the IIA.

- The IIA form must be officially signed by the PI and the individual investigator in the applicable locations.
- The study team should upload the IIA form in section 3 of the Local Site Documents page along with the individual's CV/Resume.
- The IRB RCA assigned to your study will combine the IIA form and CV/resume into one document and send to the IRB Assistant Director for approval and signature.
- Once the combined document is fully signed, then the IRB RCA assigned to your study will send it back to the study team using the Request Pre-Review Clarification function and ask that this signed document is uploaded in section 3 of the Local Site Documents in place of the old documents.

IIA individuals will still need to have the appropriate human subjects training and added to as a Study Team Member. If an individual meets the definition of either of the two types of independent investigators above, contact the IRB Reliance Manager at RSCH-Reliance@usf.edu to determine the training and documentation that will be required.

Reminders, Tips & Tricks for Success

Included below are a few reminders and tips to support our community in their research:

- Study teams are reminded that the USF IRB requires USF investigators to use the USF study protocol templates when completing IRB applications in BullsIRB. The protocol templates are available in the BullsIRB Library.
    - Sample protocols are also provided, to assist our research community with protocol creation.

- If study team members need to update either their CV/resume or their human subjects research protection certification (e.g. CITI certificate) in their ARC profile, please email a copy of the relevant documentation (CITI certificate or CV/resume) to RSCH-ARC@usf.edu.
    - Once received, our Help Desk team will update the information in your ARC profile, which is linked to the BullsIRB system.
        - Please allow 2-3 days for the system to populate your document.

- Please note that the "Add Comment" activity in BullsIRB, available for all study submission types (initial studies, modifications, continuing reviews, etc.), is part of the regulatory record, and should *not* be used as a communication channel between study team members, organizational (department) approvers, or affiliate approvers.

    - These comments are public, permanent, and should only be used to communicate with IRB personnel.
        - If you have questions about your application, send an email to the RCA assigned to your study.

- Please be aware that if you will be submitting a grant proposal that includes human research and has individuals from other organizations on the grant, you must obtain an IRB budget and letter of support to be include with the proposal submission.
    - All requests can be sent to the Reliance Inbox, rsch-reliance@usf.edu. Please make sure to include a copy of the proposal, title of the project, names of the other sites and the number of years the project will be open.
        - Be aware that it can take a couple of days to get the budget and letter prepared so please plan accordingly.

Webinar Session: Research Integrity & Compliance Overview

Research Integrity and Compliance (RIC) wants to inform the USF community of our new educational webinar sessions. These overview webinar sessions offer a comprehensive look into the various programs within RIC and are presented by experts in the field on our Applications for Research Compliance system (ARC), human and animal research, safe laboratory practices, conflicts of interest, research misconduct, mentor/mentee relationships and responsibilities, authorship and publications, collaborative research, and peer review of research. All USF faculty member, staff, and students are welcome to attend this webinar.

Individuals can attend as many or as few sessions as they like, but please register separately for each session you plan to attend. Registration links are below.

Export Control Overview – February 6th 10 a.m. – 11 a.m.
Presenter – Fred Pfleuger
USF Export Control Officer

Description: *Learn about export control regulations from the university's Export Control Officer.*
Export Control Overview-Register HERE

Overview of IACUC Services – February 13th 10 a.m. – 11 a.m.
Presenter – Farah Moulvi
USF IACUC Program Manager

Description: *Hear from the* Institutional Animal Care and Use Committee (IACUC) *Program Manager on how the IACUC can assist you with your research projects involving live, vertebrate animals.*
Overview of IACUC Services-Register HERE

Overview of Conflicts of Interest in Research – March 5th 9 a.m. – 10:30 a.m.
Presenter – Phil Olcese
USF COI Program Manager

Description: *Learn how to disclose and mitigate any potential research-related conflicts of interest from the Conflicts of Interest (COI) Program Manager.*
Overview of Conflicts of Interest in Research-Register HERE

ARC Training – April 18th 10 a.m. – 11 a.m.
Presenter – Tony Marshall
USF Technology & Systems Manager

Description: *Need help navigating the* Applications for Research Compliance (*ARC) portal? Get a hands-on lesson from the Technology & Systems Manager.*
ARC Training-Register HERE

For any questions on these educational webinar sessions, please contact RIC Director, Dr. Jay Ramage at jramage@usf.edu.

Reminder: USF Responsible Conduct of Research Education

As a reminder, USF Research Integrity & Compliance (RIC) RCR Spring 2024 sessions for our RCR training series starts this month! Attendance at each session will satisfy one (1) credit hour for RCR training. Certificates of completion for each RCR session will be issued to attendees. A combination of these training sessions will fulfill both NIH and NSF RCR training requirements. Registration links are below.

Individuals can attend as many or as few sessions as they like, but please register separately for each session you plan to attend.

Overview of RCR and Research Misconduct –Tuesday, January 11th 10 a.m. - 11a.m.
Presenter – Jay Ramage, Ph.D.
Research Integrity and Compliance (RIC) Director

Description: *Learn about conducting research in an ethical and responsible manner, and how to avoid research misconduct, from the RIC Director.*
Register HERE: Overview of RCR and Research Misconduct

Industry Collaborations– Thursday, February 15th at 1p.m. – 2p.m.
Presenter – Michele Tyrpak
Tech Transfer Director

Description: *Come listen to the Tech Transfer Director discuss collaborations with industry partners.*
Register HERE: Industry Collaborations

Biosafety Overview – Wednesday, March 27th at 2p.m. - 3p.m.
Presenter – Debbie Howeth
USF Biosafety Program Manager

Description: *Get an overview of safe practices when working with biological materials from the Biosafety Officer and Program Manager.*
Register HERE: Biosafety Overview

The IACUC – Tuesday, April 2nd at 10:30 a.m. – 11:30 a.m.
Presenter – Jay Dean
USF IACUC Chair

Description: *Hear from the Institutional Animal Care and Use Committee (IACUC) Chair how the IACUC provides oversight of your animal research.*
Register HERE: The IACUC

For more information on RCR requirements and offerings, please visit our website. For any questions, please contact Dr. Jay Ramage (RIC Director) at jramage@usf.edu.