2019

2019 Spring Newsletter

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UNIVERSITY OF SOUTH ALABAMA

Research Compliance & Assurance

SPRING 2019 NEWSLETTER

Human Subjects Research and Revised Common Rule

The IRB has revised its policies and processes to be fully compliant with the Revised Federal Policy for the Protection of Human Subjects in Research ("revised Common Rule"), effective January 21, 2019. The Common Rule revisions do not apply to Exempt studies or FDA-regulated studies, unless they are federally-funded research. The Common Rule regulations are separate from FDA regulations. FDA regulations have NOT changed; however, the FDA may harmonize their regulations to the Common Rule in the future. Specifically:

The most important points-

- USA IRB has updated or created new IRB applications to facilitate review and management of specified human subject's research projects. This includes an updated Exempt application, new application for Retrospective Medical Records Review and new application for Use of Biological Specimens.
- USA IRB has updated its consent templates and checklist
- Many more studies will qualify for exempt status.
- Continuing review reports will no longer be required for many studies (expedited studies). The IRB Office will continue to track these studies where continuing review is not required by requesting completion of an Annual Check-In form to designate the status of the study.
- Consent forms and processes must now include a Key Information section, per USA IRB policy this section is only required if the consent is greater than four pages. Per the Common Rule revisions, informed consent must begin with a concise and focused presentation of "key information" that will assist a subject in understanding reasons why one might/might not participate in the research.
- Additional consent elements are required as applicable to the research study that primarily involve the use of biological specimens.

The IRB Exempt application has been completely revised, expressly to designate when certain categories of research Exempt 2(iii) and 3(iii) are being conducted and now require additional information to be collected to ensure adequate provisions to protect privacy of subjects and maintain confidentiality of data. The form is self-guided to help the researcher comply with these requirements, if applicable. All exempt categories are now listed on the IRB Exempt

application as a result.

More information regarding the Common Rule revisions is posted on the USA IRB site under Common Rule Revisions.

IRB Policies and Procedures

The Office of Research Compliance and Assurance has reorganized the IRB policies and procedures from a comprehensive lengthy manual to individualized policy and procedure documents. The IRB policies and procedures are now affiliated with a specific category and a policy number. The reorganization of these documents provide for greater accessibility and use of this important information that impact human subject's research. Please visit the IRB Policies and Procedures webpage to access the documents. Additionally, guidance documents will be accessible from this site.

We Can Help By Speaking With Your Class About IRB

Faculty, do your students need to submit an IRB application and need guidance associated with the IRB submission process? The Office of Research Compliance and Assurance and the IRB Office is available to speak to your class. To request an IRB presentation for your class, or for more information, contact irb@southalabama.edu or dlayton@southalabama.edu

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Institutional Biosafety Committee

New Autoclave SOP

The USA Institutional Biosafety Committee has adopted a new Standard Operating Procedure for Autoclave Safety and Operation. This SOP will be located next to all autoclaves that are used for research purposes. Principal Investigators and supervisors are responsible for reviewing this SOP with all personnel that will be utilizing autoclaves. There is a training log that must be signed indicating personnel has reviewed the Standard Operating Procedures: Autoclave Safety and Operation document and understand the potential risks associated with using an autoclave. This training log needs to be maintained in the laboratory and made available during annual IBC inspections. *Standard Operating Procedures: Autoclave Safety and Operation*

National Science Foundation Policy on Harassment

The National Science Foundation (NSF) will not tolerate sexual harassment, other forms of harassment, or sexual assault within the agency, at awardee organizations, field sites, or anywhere NSF-funded science and education are conducted. U.S. institutions of higher education and other organizations that receive NSF funds are responsible for fully investigating complaints and for compliance with federal non-discrimination laws, regulations, and executive orders. As announced in Important Notice 144, NSF has taken steps to help ensure research environments are free from sexual harassment. NSF is working to ensure recipients of grants and cooperative agreements respond promptly and appropriately to instances of sexual harassment, other forms

of harassment, or sexual assault. As announced in the Federal Register on September 21, 2018, a new award term and condition has been finalized that will require awardee organizations to notify NSF of any findings/determinations of sexual harassment, other forms of harassment, or sexual assault regarding an NSF funded PI or co-PI.

The award term also requires the awardee to notify NSF if the PI or co-PI is placed on administrative leave or if the awardee has imposed any administrative action on the PI or any co-PI relating to any finding/determination or an investigation of an alleged violation of awardee policies or codes of conduct, statutes, regulations, or executive orders relating to sexual harassment, other forms of harassment, or sexual assault. The term and condition took effect on October 22, 2018.

Of importance, the award term and condition, the newly revised Proposal and Award Policies and Procedures Guidelines, which is effective for proposals submitted or due on or after January 28, 2019, has been updated to include the following:

New coverage has been added to the conference proposal section to require proposers to have a policy or code-of-conduct that addresses sexual and other forms of harassment and that includes clear and accessible means of reporting violations of the policy or code-of-conduct. This policy must be disseminated to conference participants prior to attendance at the conference as well as made available at the conference itself

For further information and the University policy and procedures for compliance with the NSF Policy on Harassment, see the Office of Research Compliance and Assurance website, Harassment Protections.

Responsible Conduct of Training Series is Still in Progress!

The 2018-2019 Responsible Conduct of Research training series is a comprehensive education program focused on topics related to the conduct of research. Research Administration highly encourages your attendance. There are three sessions remaining in this year's series which include: *Key Factors for Successful Mentor/Mentee Relationships, Conflict of Interest, and Misconduct in Science*. Detailed information, dates and registration information are available at https://www.southalabama.edu/departments/research/research-training-resources/responsible-conduct-of-research-trng-2018-2019.html**. Due to limited space and accommodation for refreshments, Registration is required.**

Hosting Visitors from Embargoed Countries

The Department of Treasury, Office of Foreign Assets Control (OFAC) broadly regulates and restricts transactions with embargoed countries including certain academic collaborations and exchange of research materials and equipment. The most comprehensive controls apply to: Cuba, Iran, North Korea, Sudan, Syria, and Crimea Region of the Ukraine.

If faculty plan to host visitors or scholars from comprehensively embargoed countries **(Cuba, Iran, North Korea, Sudan, Syria, and Crimea Region of the Ukraine), the** Office of Research Compliance and Assurance **must be contacted first.**

Items of Interest

- **DHHS Office of Research Integrity Releases New Infographics**

The Division of Education and Integrity in the federal Office of Research Integrity has generated series of infographics and integrity in science research videos. These educational materials on ethical issues that can arise in research can be used as supplemental teaching aids and instruction. See the Infographics webpage to access these educational resources.

- **DHHS Office of Human Research Protections, Exploratory Workshop**

The Office of Human Research Protection's second annual Exploratory Workshop, ***"Privacy and Health Research in a Data-Driven World,"*** will take place **September 19, 2019**. The event will be webcast live and access is free. More information will be posted here as it becomes available: **https://www.hhs.gov/ohrp/education-and-outreach/exploratory-workshop/index.html**.

- The American Statistical Association's points to caution in interpreting p-values. Read article here.
- NIH shutdown a $100M study on health effects of alcohol due to unmanaged conflicts of interest. Read New York Times article here.
- Interesting case study in research design and interpretation: The NPR article and the source paper in the *British Medical Journal*
- Recommended reading – The Code of Misconduct

- Potential FERPA violation in research conducted as a class project at Portland State University. Read article here.

Office of Research Compliance and Assurance: Committees and Programs

IRB - Human Subjects Protection

IACUC - Animal Care and Use

IBC - Biosafety

Responsible Conduct of Research

Research Misconduct

Conflicts of Interest in Research

Export Controls

Have a Question or a Comment?

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