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2020 Summer Newsletter

Dusty Layton

Angela Williams

UNIVERSITY OF SOUTH ALABAMA
Research Compliance & Assurance

COVID-19 and Regulatory Research Activities

The Office of Research Compliance and Assurance page serves as your most up-to-date information on how COVID-19 may impact regulatory research activities. Research administration has continued operations throughout this critical period, without interruption. Research compliance staff recognized their critical mission remained unchanged. Like everyone, we are adapting to change effectively and efficiently by working remotely. The staff has remained vigilant and commitment to ensuring the University conducts research activities consistent with institutional and regulatory requirements.

COVID-19 research proposals are considered time sensitive and are considered priority reviews, to facilitate a quick turnaround time. Research Compliance has also optimized its processes in reviewing PI-initiated human subjects' research studies that require local USA Data Safety Monitoring Board (DSMB) review. The DSMB evaluates research data on an ongoing basis to assure participant safety and study integrity. This process allows submissions to the USA IRB and USA DSMB concurrently rather than sequentially. Facilitating regulatory committee reviews on a parallel track, to the extent possible, will enhance the timeliness of the overall review and approval process. We would like to extend our appreciation for the efforts and commitment to our healthcare workers in the USA Health System and members of our regulatory committees, notably the Institutional Review Board, Data Safety Monitoring Board, Institutional Animal Care and Use Committee, and Institutional Biosafety Committee. To date, sixteen COVID-19 related projects have been reviewed and approved.

As always, if there are special requests or any other assistance needed, please contact the Office of Research Compliance and Assurance we will be happy to

help. Everyone stay healthy and take care during these unusual circumstances.

When a Research Subject Cannot Physically Sign Informed Consent

Informed consent must be signed by all adult research subjects prior to enrollment in a study unless the IRB approves a waiver of documentation for informed consent. In instances of research, if an individual is unable to actually sign consent because of a physical ability, mental competency, etc., it may not be justifiable for waiving consent documentation. Rather, these individuals who have experienced medical conditions or injuries may be able or have mechanisms that allow this subject population to provide a signature. Specifically, the USA IRB allows any mark by the research subject to fulfill the signature requirement. If the subject is not able to make a mark (typically an "X") of any type on the consent, a witness must then participate in the consent process. The role of the witness is to observe consent documentation, the subject's verbal agreement, and the witness must sign and date the consent document. In these circumstances, a witness signature can be inserted by pen if warranted. Finally, documentation is critically important and the research record should include the circumstances associated with the evaluation of a subject's physical condition.

If a potential subject does not have physical limitations to prevent signing or

making a mark on the consent document, and resist to sign on their behalf, the consenting process must be stopped. A potential subject cannot be enrolled in a study until the research site submits an amendment to the IRB seeking approval to enroll the subject without obtaining a signature or grant permission by another individual to sign, regardless of the subject's condition to sign on their own behalf.

Documenting the Informed Consent Process

To many, the term *informed consent* is mistakenly viewed as the same as getting a research participant's signature on the consent form. FDA believes that obtaining a research participant's verbal or written informed consent is only part of the process.

For FDA-regulated studies, the FDA expects that "the case history for each individual shall document that informed consent was obtained prior to participation in the study". Furthermore, by documenting the informed consent process, the Investigator is able to demonstrate that no research procedures were completed prior to the subject providing their consent.

Additionally, for non-FDA-regulated studies, study teams should also consider

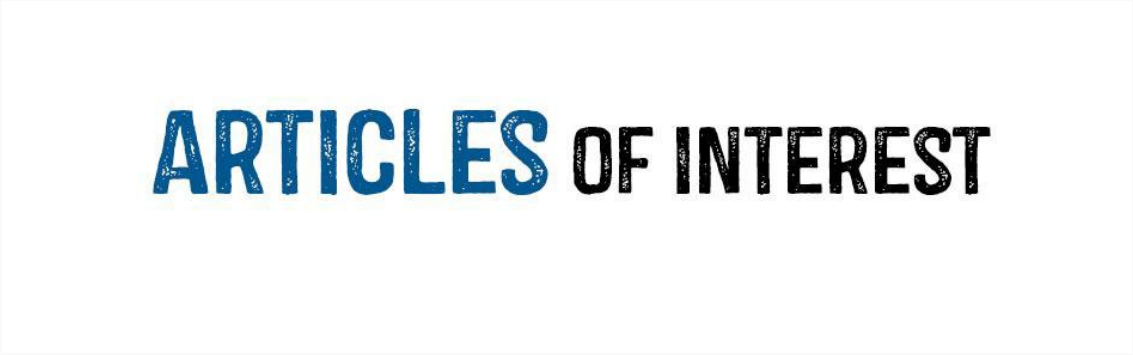
documenting the consent process. This is particularly helpful for any outside reviewers to efficiently determine that informed consent rules were followed.

For more information, including a standardized Informed Consent Process Documentation form can be found on the Informed Consent information tab on the Research Compliance website.

Export Control Research

As a reminder, a Technology Control Plan (TCP) is required for all export-controlled research. A TCP is a customized management plan which outlines the procedures in place to prevent access to export-controlled items, technologies, data, or information by unauthorized individuals. In short, Export Controls regulate the shipment or transfer, by whatever means, of controlled items, technology, software, or services outside of U.S. (termed an "Export"). Possibly of even a greater effect on the university, is restrictions imposed by the government associated with the release of certain information to foreign nationals in the U.S. (referred as a "Deemed Export"). What does this mean? The export control regulations state that Deemed Exports may happen when an individual from a particular barred (defined by the sponsoring agency or the US government) country of origin obtains access, data, or knowledge with restricted equipment, materials, technology, and by visual inspection without direct contact of the items.

A Technology Control Plan must include a pre-approved list of personnel who is granted permission to work on the research project. Project personnel are required to read and sign the TCP, as well as annually. The Principal Investigator must notify the Office of Research Compliance and Assurance of any personnel changes (additions and removal) so that the TCP can be updated and approved.



Applicant/Recipient COVID-19 Update History

Grants administration guidance to the community regarding COVID-19 is rapidly evolving. Use this high-level summary of NIH updates to identify what's new.

Saliva Test for COVID-19 Approved for Emergency Use by FDA

What Do Antibody Tests For SARS-CoV-2 Tell Us About Immunity?

To accelerate innovation, the CDC should ease limits on which labs can handle the coronavirus

COVID-19: New animal data back up Gilead's remdesivir as other treatment candidates emerge

From mice to monkeys, animals studied for coronavirus answers

Our mailing address is:
University of South Alabama
307 N University Blvd
AD 240
Mobile, AL 36688-3053
Add us to your address book