
April 2020 Edition

USF IRB Newsletter

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



USF IRB SARS-CoV-2 (COVID-19) Guidance for the Research Community

The health of our community is critically important to us. During this public health emergency, we recognize that many researchers may have questions about what must be reported to the USF IRB and when. As such, we have created guidance about how severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) may impact human subjects research and USF IRB reporting requirements. The guidance document can be found [HERE](#).

If you need to contact the USF IRB, please be advised that the staff members, Chairs and Vice Chairs are working remotely. If you have an urgent issue on which you need guidance, please send an e-mail to RSCH-IRB@usf.edu and an IRB Manager will respond as quickly as possible. Applications, including initial applications and modifications, are being processed in the order in which they are received.

If you need to make emergency revisions to your currently-approved protocol as a result of COVID-19, please send an e-mail to RSCH-IRB@usf.edu and provide the name of the Principal Investigator, study title and protocol number (Pro XXX or Study XXX) and the reason you are requesting an expedited review and we will do our best to accommodate your request.

Other USF HRPP program staff members and ARC team members are also working remotely and can be reached via the following e-mail addresses:

- For information/questions about single IRB review: RSCH-Reliance@usf.edu
- For information/questions about BullsIRB: RSCH-ARC@usf.edu
- For information/questions on research-related conflicts of interest (COI): COI-Research@usf.edu
- For information/questions on HIPAA: hipaa-research@usf.edu
- For information/questions on quality assurance: QA-QI@usf.edu

FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic:

The FDA recognizes that the COVID-19 pandemic may impact the conduct of clinical trials of medical products, and as such, an [FDA outline of general considerations](#) has been created to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice (GCP), and minimizing risks to trial integrity. Vigorous efforts by sponsors, investigators, and IRBs/IECs to maintain the safety of trial participants and study data integrity are expected, and such efforts should be documented. The FDA guidance document indicates that protocol modifications may be required, including unavoidable protocol deviations due to COVID-19 illness and/or COVID-19 control measures. Efforts to minimize impacts on trial integrity, and to document the reasons for protocol deviations, will be imperative.

CDC Guidance on Reducing Stigma related to the COVID-19 Pandemic

Public health emergencies, such as the outbreak of coronavirus disease (COVID-19) are stressful times for people and communities. Fear and anxiety about a disease can lead to social stigma toward people, places, or things. For instance, stigma and discrimination can occur when people associate a disease, such as COVID-19, with a population or nationality, even though not everyone in that population or from that region is specifically at risk for the disease. Stigma can also occur after a person has been released from COVID-19 quarantine even though they are not considered a risk for spreading the virus to others. In addition, someone who has been released from isolation is not considered to pose a risk of infection to others.

Some groups of people who may be experiencing stigma because of COVID-19 include:

- Persons of Asian descent
- People who have traveled
- Emergency responders or healthcare professionals

Stigma hurts everyone by creating fear or anger towards other people. Everyone can help [stop stigma related to COVID-19](#) by knowing the facts and sharing information with others in your community.

The International Compilation of Human Research Standards

Important for investigators who conduct research internationally, the 2020 edition of the International Compilation of Human Research Standards has been released and is now available on the U.S. Department of Health and Human Services web-site found [HERE](#).

The Compilation is a listing of over 1,000 laws, regulations, and guidelines on human subjects protections in 133 countries and from many international organizations. Most of the listings provide hyperlinks to source documents. These laws, regulations, and guidelines are classified into nine categories:

1. General (i.e., applicable to most or all types of human subjects research)
2. Drugs and Devices
3. Clinical Trial Registries
4. Research Injury
5. Social-Behavioral Research
6. Privacy/Data Protection
7. Human Biological Materials
8. Genetic
9. Embryos, Stem Cells, and Cloning

Prepared by the Office for Human Research Protections of the U.S. Department of Health and Human Services, the Compilation is designed for use by IRBs, researchers, sponsors, and others involved in human subjects research around the world.

