USF IRB SARS-CoV-2 Guidance for the Research Community
UPDATED 4.1.2020

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 would like to share this guidance about how severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes the disease known as COVID-19, may impact human subjects research and USF IRB reporting requirements.

**Should I continue my ongoing study?**
At this time, USF remains open and has not placed any restrictions on ongoing research. We strongly advise researchers to consider the risk-to-benefit ratio when considering whether to continue a particular research study. Researchers conducting studies offering minimal benefits to participants should consider temporarily pausing study activities in order to minimize risks to current and potential participants.

**When do I need to obtain prospective approval from the IRB to make a change to my currently approved research and how do I do so?**
USF IRB policies and procedures require prospective approval from the IRB before making a change to research unless necessary to eliminate apparent immediate hazards to participants. During the SARS-CoV-2 pandemic, Principal Investigators are responsible for determining whether a particular circumstance requires a deviation from the approved protocol to eliminate an apparent immediate hazard. Any protocol deviations made to eliminate an apparent immediate hazard must be reported to the USF IRB by completing and submitting a Reportable New Information (RNI) SmartForm in BullsIRB within five (5) business days of the study team’s knowledge of the event. How to submit an RNI is outlined in the HRP-103 – INVESTIGATOR MANUAL.

**I want to modify my approved protocol to conduct study visits virtually and/or collect data remotely. What do I need to consider before submitting a modification to the IRB?**
Study teams proposing to use technology to facilitate virtual study visits and/or collection of data from participants should consider the following:
- How participants’ privacy will be protected during virtual study visits;

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• How confidentiality of participants’ data will be maintained;
• Whether, given the nature of the research, the technology must be HIPAA compliant;
• If informed consent is being obtained, whether re-consent is required.

Modifications submitted to the IRB must include an updated, tracked changes version of the protocol and, if applicable, an updated tracked changes version of the consent document in addition to the clean version. If editing the consent form or writing a notification memo to study subjects regarding the new online procedures, please include the following language:

“If completing the study online, it is possible, although unlikely, that unauthorized individuals could gain access to your responses. Confidentiality will be maintained to the degree permitted by the technology used. No guarantees can be made regarding the interception of information sent via the Internet. However, your participation in this study involves risks similar to a person’s everyday use of the Internet.”

Researchers conducting studies subject to the HIPAA Privacy Rule should make every effort to utilize technology that is HIPAA-compliant. The following list includes vendors that represent that their products are HIPAA-compliant:

• Skype for Business
• Microsoft Teams
• Zoom for Health
• Google G Suite
• REDCap

If Investigators are in possession of signed informed consent forms that they are unable to store at their campus office due to the COVID-19 pandemic (or if a student, their Faculty Advisor’s office), consent forms may be stored in the interim at the Investigator’s home residence, as long as there is a double-lock procedure in place. This means that the consent forms are stored in either a non-shared locked drawer, cabinet, home office, etc. that is also behind another locked door (i.e. a locked front door or another locked room door). Please note that once the Investigator has access to their campus office, consent forms should be transported and stored at their campus office.

**Screening for SARS-CoV-2 is required by my institution, do I need to submit a modification to the IRB to include this in my protocol?**

If your institution/clinic is requiring all patients to be screened for the novel coronavirus for clinical purposes, such screening is considered standard of care and does not need to be reviewed and approved by the IRB. If you want to implement novel coronavirus screening into your research protocol, you must complete and submit a Modification SmartForm in BullsIRB and obtain prospective approval **before** implementing the screening. How to submit a modification is outlined in the HRP-103 – INVESTIGATOR MANUAL.

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How do I report deviations related to SARS-CoV-2?
During this pandemic, some studies may experience an increase in minor deviations due to participants’ unwillingness or inability to present for study visits. Minor deviations must be reported to the IRB during a study’s continuing review. Study teams whose studies require continuing review must complete and submit the Continuing Review SmartForm in BullsIRB as outlined in the HRP-103 – INVESTIGATOR MANUAL.

When and how do I report study suspensions or holds?
During the pandemic, some studies may voluntarily halt subject enrollment or participation. This must be reported as follows:

1) Suspensions or holds of research for non-interventional studies, studies with no subjects enrolled, or studies in which research-related interventions have not yet started or are complete:
   • For expedited studies reviewed under the 2018 Common Rule for which a continuing review is not required, suspensions or holds must be reported via the RNI SmartForm within five (5) business days of becoming aware of the suspension or hold.
   • For studies reviewed under the pre-2018 Common Rule or the 2018 Common Rule for which a continuing review is required, suspensions or holds can be reported during the next continuing review.

2) Suspensions or holds of research for which subjects are currently receiving research-related interventions must be submitted to the IRB via the RNI SmartForm within five (5) business days of becoming aware of the suspension or hold.

3) Suspensions or holds of USF research subject to oversight of an external IRB:
   • For minimal risk research do not need to be reported to the USF IRB.
   • For greater than minimal risk research, must be reported to the USF IRB via the RNI SmartForm within ten (10) business days of becoming aware of the suspension or hold.

I want to use a non-FDA approved product to treat a patient diagnosed with COVID-19. Do I need to obtain prospective approval from the IRB?
During the pandemic, emergency use and expanded access requirements remain unchanged. Whether prospective IRB approval is required depends on the facts and circumstances of each particular case.

Federal regulations and USF IRB policies require notification of the IRB prior to the emergency use of a drug, biologic or device unless there is not sufficient time to obtain prospective concurrence from the IRB Chair. Specific criteria must be met in order for an unapproved drug or biologic to be eligible for emergency use. Investigators should reference HRP-322 – WORKSHEET – Emergency Use for the criteria and HRP-103 –
INVESTIGATOR MANUAL for additional information on emergency use requirements. HRP-200 – FORM – Emergency Use of a Test Article must be completed and submitted to the IRB at RSCH-IRB@usf.edu prior to the proposed emergency use or, if such use occurs after business hours, within five (5) business days of the use, to obtain concurrence of the IRB Chair.

Expanded access use of a drug or biologic requires prospective IRB approval. To obtain prospective IRB approval, an application containing a protocol and a consent document must be submitted via BullsIRB.

Contact the IRB directly with questions regarding emergency use or expanded access requirements: RSCH-IRB@usf.edu.

How do I contact the USF IRB if I have a question about my research?
USF IRB 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. However, if you need to make revisions to your currently approved protocol as a result of SARS-CoV-2 and need prospective IRB approval before implementing the revisions, 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): CoiResearch@usf.edu
- For information/questions on HIPAA: hipaa-research@usf.edu
- For information/questions on quality assurance: qa-qi@usf.edu

For the latest updates from USF on the coronavirus and the University’s response, visit www.usf.edu/coronavirus.

References:
FDA Guidance on Conduct of Clinical Trials of Medical Products During COVID-19 Pandemic; Notification of Enforcement Discretion for telehealth remote communications during the COVID-19 nationwide public health emergency