MUSC IRB Message to Researchers Re: COVID-19

- Researchers should submit amendments to the IRB for review (per federal regulations) and approval when/if needed to make changes to the research in response to COVID-19 issues (e.g. decreasing protocol-mandated in-person visits, shipping investigational products directly to research participants, implementing telemedicine visits).

  Note: This applies when halting study procedures may impact participant safety (e.g., unable to collect safety labs or conduct physical examinations).

- If a researcher needs to make a change in research due to safety concerns with no time to notify the IRB for approval of the change, the researcher may implement the change(s) to research plans to eliminate the risk. Researchers may notify the IRB via a protocol deviation. The protocol deviation should include a summary for all changes rather than submitting multiple deviations for each deviation that may have occurred. Researchers do not need to submit a separate protocol deviation for each subject affected by the deviation. The deviation may apply to all subjects affected by the change.

  Note: While the PI should maintain some log of the subject ID information for future reference and subsequent audits, the subject IDs do not need to be listed on the deviation summary.

- For ongoing changes, the researcher must submit an amendment to the IRB immediately (within 5 days) of the changes for review and approval of the updated study procedures.

COVID-19 Amendment Submission Instructions

- Amendments that are submitted in response to the developing COVID-19 pandemic will be given the highest priority. We are all in new territory in the midst of this pandemic and are working to develop internal procedures that will allow us to process these requests in the most expeditious way possible. Here are a few ways that you can help:

  1. Please customize the "Name" of your amendment in the eIRB SmartForm to include "COVID-19". This will make it easier for IRB staff to identify that the amendment is a change that is being made in direct response to the virus.

  2. If you will be adding electronic consenting to your study, please remember that you will need to alter the eIRB SmartForm. Depending upon the remote consent platform you choose, your current ICF may require formatting changes outlined in the guidance on the IRB website.

  3. Protocol updates: Please make sure the protocol is updated to include applicable information concerning the changes that are being requested, if you are incorporating e-consent then that will be explained in the protocol's consent process section; telehealth visits should be explained in the protocol's procedures section.

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4. As with all amendments, please make sure that all impacted eIRB SmartForms are updated for consistency.

The following are situations in which the IRB does not need to be notified:

- Implementation of clinical screening procedures related to COVID-19 at healthcare facilities for all patient-related visits including research visits.
    - These procedures are not considered part of "IRB approved procedures" for individual protocols and would not require IRB reporting.
    - An exception to this would be situations in which the investigator incorporates the data collected under these clinical procedures into their individual protocol (i.e. adding a research objective of analyzing the results of the clinical screening procedures based on subject demographics). Investigators are encouraged to contact the IRB prior to collecting and analyzing the data collected from COVID-19 clinical screening as part of their current IRB approved protocol. An IRB approved amendment would be required to prior to implementing these changes.

- Amendments/status updates are not required if temporarily halting subject recruitment, rescheduling, or delaying study enrollment unless those actions are at the request of the funding agency, study sponsor, or data and safety monitoring group.

"Remote" Informed Consent for Studies Requiring a Signed Consent

- Depending upon the risk of the study and activities, consent processes may not be able to be waived or altered per federal regulations. For example, studies conducted under an IND, IDE, or other "greater than minimal" risk activities (i.e. Full Board Review) require a written signature be obtained prior to beginning research procedures. Therefore, a verbal consent from the participant cannot replace the signed consent form.

- To conduct consent remotely, an amendment is required as the new consent plan needs to be approved by the IRB. The remote consent process should include an informed consent discussion with the potential participant and involve the participant signing and returning the informed consent document to the researcher. The informed consent discussion can occur over the phone or by secure video conferencing platform. The documentation of consent process should include sending the informed consent document to the subject for signature and transmitting it back to the research team to be signed by the researcher before any research procedures begin. The document could be sent by mail or by using one of the electronic consent options described in the following section. The procedures for the informed consent discussion and obtaining signatures (documentation of consent) should be clearly described in the amendment.

- Below is information from the Electronic Consent Guidance Document on the IRB's Website:

What types of electronic consent systems are currently available at MUSC for researchers' use?

A: Currently, the MUSC IRB has approved the use of the REDCap system and Doxy.me

There are other electronic consent systems that are commercially available. For a system that has not been used at MUSC, the MUSC IRB would have to evaluate the system upon review of study. This review may entail the investigator working with other areas on campus to ensure information security, etc.

Below details information regarding the use of the REDCap system for electronic consent:

- The REDCap template for creating an eConsent database is available from the Template List on the "New Project" page within REDCap. The template is called MUSC eConsent Project Template. It includes Standard Operating Procedures (SOP) for the customization and use of the database. Both regulatory and REDCap assistance are available if needed via the SCTR SUCCESS Center by submitting a SPARCRequest and requesting the appropriate consultation(s).

The MUSC Biomedical Informatics Center has a tele-consent platform that is available for use by MUSC researchers. This platform is called Doxy. To receive information regarding the use of the Doxy.me system for electronic consent, please submit a SPARCRequest or contact one of the below individuals

- Brandon Welch: welchbm@musc.edu or 843-792-5452
- Jihad Obeid: jobeid@musc.edu or 834-792-0273

Single IRB (sIRB) Issues/Reliance on an External IRB

- For sIRB studies, local context considerations must govern what research activities are permitted at each site.
  -A reviewing IRB should not override the determination of a local organization that research activities must be restricted.

- Investigators are encouraged to share local contingency plans with external IRBs
  -Should affirm whether the reviewing IRBs reporting requirements differ from their local plans

- For questions related to Single IRB (sIRB) Issues/Reliance on an External IRB, please contact Summer Young at 843-792-4144 or youngsn@musc.edu.

If you have any questions about MUSC IRB policy on changes to research or the acceleration of review for COVID-19 research, please reach out to the IRB at 843-792-4148.

Remember reporting to the IRB is independent of any reporting requirements required of investigators by the funding agency or sponsor for a protocol.

We share in everyone's concern for the wellbeing of our community and will be making every effort to assist our study teams in incorporating these necessary changes in a timely fashion.