

The Institutional Review Board

November 2020

It has been a year filled with uncertainty and as the New Year approaches, we look forward to the coming months with hope and anticipation. It continues to be a privilege to work with the research community, and while the holidays may look different for a lot of us, we hope the wonder of the season brings you joy in unexpected ways.

Wishing you and yours the happiest of holidays and a healthy New Year!

IRB Updates

COVID-19 Initial Studies Reminder

All COVID-19 studies submitted to the IRB will need to include "COVID" in the short title of the study application for quick identification and reporting purposes.

Updated Meeting Dates and Deadlines

We have updated our website with the 2021 Meeting Dates and Deadlines for IRB submissions. Please see the link below:

IRB Meeting Dates & Deadlines

External IRB Reliance - SCTR Lunch & Learn

Summer Young, the IRB Reliance Manager, will be giving a Lunch & Learn on IRB Reliance on an External IRB. It will take place on February 10, 2021 12:00 - 1:00PM. We invite all those who would like to attend to register via the SCTR Lunch & Learn website.

SCTR Lunch & Learns

Quality Improvement vs. Research

Quality Improvement (QI) activities are usually done for internal purposes only and meant to improve the quality of programs, services, or provision of medical care or customer service. QI projects may not always meet the definition of research, which is to help develop new knowledge that can be generalized to other similar populations and settings. However, some QI projects may fall under the federal definition of human subject's research, and therefore may require IRB review.

To help determine if your study is QI or research, you can use the QI Program Evaluation Self-Certification Tool. The QI Tool (a REDCap form) will help determine if you need to submit an IRB application, or it will provide you with a certification letter stating that your project does not constitute as research and does not need IRB review. A link to the QI Tool and the IRB policy are provided below.

IRB HRPP 3.8 - Quality Improvement Projects

QI Program Evaluation Self-Certification Tool

Uploading Documents in eIRB for IRB Approval Stamping

Some documents that are submitted in an IRB application, such as recruitment materials, require an IRB watermark. The watermarks are stamped by the IRB upon approval of the study or the amendment. Document stamping can be performed on PDF and word documents, but there is a different process for each type.

If you upload a PDF:

- Documents must be uploaded in eIRB with no watermark stamp template in the PDF, just the MUSC logo.
- Word documents with the stamp should not be converted to PDFs and reattached (with the stamp template still included).
- There should not be any content at the bottom of the document where the stamp will be placed except the MUSC logo.
- The system places an image of the stamp (PRO number and approval date) into the center of the footer of the document.
- The stamp is based on the format provided to the eIRB development team and necessitates a development change to update.
- The IRB Staff cannot change the placement of this stamp.

If you upload a Word Document:

- The watermark stamp template is required within the draft document.
- <u>Note:</u> The template must be an editable text box, *NOT* an image of the stamp template.
- The eIRB system applies the details (PRO number and approval date) and render the document in the specified format (Word or PDF)

For more information, please see the link below:

eIRB: Uploading Documents for IRB Approval Stamping

Reliance on an External IRB

If you plan to use another IRB for oversight of your study, you still need to submit your protocol to the MUSC IRB. MUSC has created a "Reliance Intake Form" (a REDCap form) that must be submitted and reviewed. You must submit your request before making any commitment that MUSC will rely on an external IRB. The MUSC IRB will review your reliance request to determine whether the institution is willing to enter into a reliance agreement. Once you have received confirmation of our willingness to enter into a reliance arrangement, you will be asked to submit an abbreviated application via eIRB. Even though another IRB has taken responsibility for the review of your research under the criteria required by the applicable federal regulations and/or HIPAA, there are still pieces of review that must occur at MUSC (local context review, ancillary review, etc.). The IRB also requests copies of the consent document, protocol, and IRB approval letter from the IRB of Record for documentation purposes.

For more information regarding Reliance on an External IRB, please see the links below.

Reliance Intake Form

IRB Reliance Requests

elRB Tip

Monitoring the Current State of Studies in eIRB

If your study application is in the Pre-Submission state, it has not yet been submitted to the IRB. The Principal Investigator is the only one with the capability to submit a study application. Please note that the IRB does not have your study until the state is IRB Staff Review.

The elRB system is state-based, which means it displays a 'Current State' that tells you where the application is in the review process at any point in time. This applies to new study applications, amendments, continuing reviews, and reportable events. Each application will transition through various states from Pre-Submission, to final states such as Approved, Acknowledged, Withdrawn and Completed.

The Current State is viewable within the column called 'State' on your homepage or when searching for projects, or on the upper left hand side of the application's workspace. Users with access to the application can log into the eIRB system and see in which state the application resides, as well as view the history showing when actions were taken on the application. Please see the links below for more information:

eIRB states

eIRB Education and Training

About the Staff

Maggi LeJeune

Maggi LeJeune is the IRB Coordinator for Board II and has been with the IRB for a year. She grew up in Lexington, SC, but spent a lot of her youth in the Lowcountry. After attending the University of South Carolina, she began her career in healthcare and decided to move permanently to Charleston. In her free time, she enjoys spending time at the beach or on the boat with her husband and two yorkies.

Contact Us

Have feedback or suggestions you would like to share? Email us at: <u>irb-news@musc.edu</u>



IRB Contacts



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