

The Institutional Review Board

February 2021



It's the IRB Newsletter's First Anniversary! We hope that this newsletter has been able to provide you with resources and guidance as you continue working in the regulatory world. Keep in mind that while we highlight topics each quarter, there are still so many to cover. Make sure you visit the IRB website and also note that the SUCCESS Center is available for consultations via a SPARCRequest.

[MUSC IRB Website](#)

[Submitting a SPARCRequest](#)

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.

Before submitting COVID-19 studies to the IRB, please check with the COVID-19 Research Review Committee for approval of these projects. See the link below for more information.

[MUSC Research Continuity & Planning for COVID-19](#)

External IRB Reliance - SCTR Lunch & Learn

Stacey Goretzka, the IRB Program 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.

If you have any questions about External IRB Reliance, please contact Summer Young, the IRB Reliance Manager, at youngsn@musc.edu or 843-792-4144.

[SCTR Lunch & Learns](#)

Important Updates to MUSC's Policy on Recruitment of Research Participants

As of January 2021, MUSC has a new policy regarding recruitment of research participants. MUSC used to be an "opt-in" institution, where patients would agree to be contacted for research opportunities through MyChart. This new policy addresses MUSC moving to an "opt-out" institution when it comes to contacting patients about research opportunities. This means that some study teams, after getting IRB approval and completing the appropriate cold-contact data request process, will be allowed to reach out to any patient who meets eligibility criteria for their projects who has not opted out of being contacted for research opportunities.

You can learn more about employing cold-contact methods for MUSC patient recruitment by visiting the South Carolina Clinical and Translational Research (SCTR) Institute's "Cold Contact Recruitment" webpage. You can also email the SCTR SUCCESS Center at success@musc.edu.

[IRB HRPP 7.8 - Recruitment of Research Participants](#)

[Cold-Contact Recruitment](#)

PI Responsibility When Leaving MUSC

It is the PI's responsibility, when leaving MUSC, to either close out their study with the IRB or transfer the study by amendment to another PI prior to leaving. If you are planning to leave the institution and still have open studies with the IRB, contact an IRB Staff Member to develop a plan for closure or a PI change amendment. It is important to note that a study should not be left to expire. Please refer to the Off-Boarding Checklist below when leaving the institution.

[HRPP 5.1- PI Responsibilities](#)

[Research Faculty Off-Boarding Checklist](#)

PI Responsibilities When Relying on an External IRB

Keep in mind that if MUSC relies on another IRB, you as the MUSC PI still retain considerable responsibility. In summary, you must:

- Ensure all members of your study team are appropriately qualified.
- Comply with the determinations and requirements of the Reviewing IRB.
- Maintain appropriate copies of all approvals, and other correspondence documenting the review and approval of the research as required by the regulations.
- Submit a modification to the MUSC IRB if/when:
 - New personnel are added to the study team.
 - The study is modified in such a way that additional institutional approvals are required (e.g., radiation safety, conflict of interest).
 - Changes are made which affect institutional policy/state law requirements.
- Report promptly to the Reviewing IRB any proposed changes in the research.
- Report to the Reviewing IRB any unanticipated problems involving risks to participants or non-compliance.
- Report to the Reviewing IRB as well as the MUSC IRB any complaints from a subject or other person regarding the research.

Please see the links below for more information.

[HRPP 9.5: Relying on an External IRB](#)

[IRB Reliance Requests](#)

eIRB Tip

Editing the Personnel List and then Lose Access to the Study?

If you are revising/editing the personnel list on a study and then lose access to continue editing the study after clicking the continue button, you may have removed or replaced yourself on the study. Because of this, the system no longer recognizes you as someone with rights to the study (you may also have been logged out of the system with no access to that protocol). To move forward, you may request someone who's listed as personnel with edit rights to add you back onto the study. Otherwise, you will need to contact your institutional eIRB administrator for assistance.

[MUSC eIRB Administrators](#)

[eIRB Education and Training](#)

About the Staff

Jackie Shedrow, CIP

Jackie Shedrow is one of the Co-Administrators for Board III. Her MUSC career started with the Pediatric Cardiology department before she made the move to the University. She has been with the IRB for 13 years. In her previous life, Jackie worked as a marketing director for several large architecture, engineering, and construction management firms. She spends her free time with family and close friends, enjoys photography, gardening, and DIY projects of all kinds.

Contact Us

Have feedback or suggestions you would like to share?

Email us at: irb-news@musc.edu

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[IRB Contacts](#)



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