

The Institutional Review Board

May 2023

While we always try to highlight the latest information with the IRB newsletter, we also want to use it to remind you of different resources that are available to you. Built within eIRB, our electronic protocol tracking system, we have a frequently asked questions (FAQs) section that you may find helpful when working on different types of IRB submissions. You can access the FAQs via the Education and Training tab at the top of your eIRB home page. Below is a quick link to the eIRB FAQs.

eIRB FAQs

IRB Updates

elRB update

We are excited to announce that the eIRB development team has scheduled a software upgrade (Portal 9.0.8) to our system during the 3rd quarter of this year. Additional information and a specific release date will be communicated promptly once available. The upgrade includes many enhancements and an updated design for Smartforms and other projects. The functionality of Smartforms, their content, and data will not be changing, however, reviewers' comments will be easier to locate for study teams' responses. To assist with the transition to the new format, the development team has created documentation for researchers and staff to review and practice the update prior to implementation. Researchers and staff are strongly encouraged to access the written documentation and corresponding video links below to view the planned system changes. Further updates and materials will be distributed through all available channels as they become available. Keep an eye on the eIRB front page as the release date will be posted there when set, along with supplemental materials for user training and education.

eIRB Portal 9.0.8 Software Upgrade Video

eIRB Portal 9.0.8 Software Upgrade Document

Privacy Compliance Reminder

All University faculty, students and staff are responsible for immediately reporting to the University Compliance Office any activity reasonably believed to be a breach of privacy caused by the unauthorized acquisition, access, use or disclosure of any personally identifiable information, including student or patient information. This report must be made in accordance with the MUSC Compliance policy and the Privacy/Security Breach Determination and Notification policy. The Compliance Office will work with you to determine whether a breach has occurred and whether any individual or regulatory notifications are required. Reporting a privacy concern may be done through any of the following methods:

- Online via the Compliance Reporting and Resource Form (musc.edu),
- Email <u>univ-compliance@musc.edu</u>,
- Telephone (843) 792-8652, or
- 24/7 calls to the Compliance Hotline 1-800-296-0269

If a breach occurred in the scope of a research project, this information should also be reported to the Institutional Review Board no later than 10 working days after it occurs, in accordance with HRPP 4.13 and HRPP 4.14.

Not Ready for Review - What does it mean and what to do?

When the IRB receives a research application prepared in such a way that the proposed research procedures are unclear, or large components of the application are missing, reviewers will be unable to provide meaningful comments and guidance. In such a case, the application will be sent back to the study team as "Not Ready for Review" (NRR) and recommendations to consult with additional institutional resources and regulatory guidance will be provided to the Principal Investigator (PI). When a study is returned in this manner, the study application will go back through the department review process. Below are some examples of scenarios in which the IRB may determine that an application is NRR:

- Missing or inadequately prepared essential documents, including:
 - o Protocol.
 - Consent Form(s),
 - Questionnaire(s) or focus group materials when the main component of the study is administration of that material,
 - Documentation needed to determine the engagement level of any off-campus study sites,
 - o Drug or device documentation.
- Inconsistent or unclear description of procedures such that the reviewers are uncertain of what is being proposed.
- Project described does not seem to constitute research with human subjects as written.
- Recurrent errors throughout the application and attachments to the extent that a
 detailed review and revision of the entire application is needed.
- Information presented in the Smartform is not in agreement with the information provided in the protocol, ICF and other supporting documents.

When an application is returned in this manner, the recommendation from the IRB to the study team is to:

- Seek help from the free research support services at the SUCCESS Center;
- If the PI is a student or trainee, talk with the PI's Mentor to receive guidance on how to provide a complete application; or
- Set up a meeting with the IRB Administrator and Chair.

Researchers who have used the SUCCESS Center services have had a higher success rate of IRB approval upon resubmission of their study applications.

SUCCESS Center

Top 10 Pitfalls of External IRB Applications

In a previous newsletter, we outlined the <u>Top 10 Pitfalls of Initial Study Applications</u> for internally reviewed research. To assist with studies that will use an external IRB, below you will find a list of tips to help move externally reviewed applications forward more quickly.

- 1. When you are determining a start date for your study, remember to factor in the time it takes for department reviews to occur. Your application won't be delivered to the IRB's inbox until all of these approvals are in place. Once the application is available for internal review, the study's state will update to: "IRB Staff Review" in eIRB.
- All reliance documentation should be sent to the MUSC Reliance Team as soon it is received so that the required forms and Reliance Agreement can be prepared. Information should be sent to <u>youngsn@musc.edu</u> when making specific reliance requests.
- 3. Take care when uploading the Reviewing IRB's approved consent template into Section 3.0 of the external application; placing the document in the wrong section will cause delays in processing.
- 4. Prepare the MUSC version of the informed consent by combining the Reviewing IRB's ICF template with local context language and upload the resulting combination document into Section 6.0 of the Smartform.
- 5. When preparing the MUSC consent form, the sponsor will provide a consent form template with certain sections that can be completed with local context language. MUSC has certain required language that must be in all consent forms. For more information, see <u>Reliance Request Frequently Asked Question #16.</u>
- 6. Also, don't forget to upload the Reviewing IRB's main study approval letter into Section 4.0 to avoid slowing the review's progress.
- 7. So that you can track your application's progress, when all institutional requirements have been met your study will enter the state of "Reliance Acknowledged, Pending Activation". This is when the study should be submitted to the reviewing IRB to be added as a research site. Remember to upload the final approved documents, including the stamped ICF and approval letter, into the application's external documents page when you receive them.
- 8. Corporate-sponsored studies require a finalized MUSC/sponsor contract before you will be provided with a "Reliance Acknowledged, Pending Activation" letter that notifies you to proceed with review by the external IRB. Do keep in mind that contract finalization often requires changes to the consent's Sponsor Commitment section.
- 9. Don't forget to submit an Annual Status Update to the MUSC IRB; timing for this is dependent on the study's expiration date at the lead site.
- 10. Finally, if changes modify the study in ways that require additional institution approvals (e.g., radiation safety, conflict of interest, a change in local context language) or staffing is changed, don't forget to submit an amendment to the MUSC IRB.

Continuing Review Number of Subjects Chart – It All Adds Up!

2.0 Number of Subjects

Note: "tast review" is the study's initial review or continuing review, whichever is most recent. For the first continuing review, the numbers will be the same in both columns.					
1.0	Number of study wide subjects approved for enrollment	314			
2.0	Number of local subjects approved for enrollment	10			
		Column A Column B Column C			

		Number since LAST Review	at LAST Review	Cumulative Number since INITIAL Review (1)	
3.0	Number of subjects enrolled study wide, or for a chart review number of records reviewed		0	0	
4.0	Number of subjects enrolled locally, or for a chart review number of records reviewed 🕞		3	6	
5.0	Number of subjects who screen failed ("0" If no screen failures or the study has no screening procedures)	2	3	5	
6.0	Number of local subjects who have completed the study (s) (Including death(s) expected as an endpoint)		1	6	
7.0	Number of local subjects who have withdrawn 9	,	0	1	
8.0	Number of local subjects who died unexpectedly		,	1	
9.0	Number of local subjects currently receiving treatment/intervention 🕟 0				
10.0	Number of local subjects currently in follow-up only 🕟 0				

[1] Cumulative Totals will be recalculated when the Continue button is selected. Otherwise, save this page for immediate recalculation of these totals

If your research study meets the criteria to require a Continuing Review, you will need to submit a Continuing Review (CR) to the IRB no later than one month before study expiration. In this CR, you will find a chart in which you will need to report the number of subjects enrolled in the study. There are several items to keep in mind while filling out this chart.

- 1. The Columns: Column A is the number of subjects reported between this CR and last CR, if you've had a previous CR. Column B is the number of subjects reported in your last CR (elRB will generate this information for you). Column C is the number of subjects cumulative for your study.
- 2. Item 2.0 Is the number of subjects you are approved to enroll in the study per the IRB-approved protocol/application (eIRB will generate this information for you). Make sure you don't over-enroll! If you do, please submit a protocol deviation and, if your study is industry sponsored research, check with ORSP to ensure the MUSC/sponsor contract will not require revision.
- 3. Item 4.0 Is the number of subjects you have enrolled locally in the study.
- 4. Item 5.0 Is the number of subjects who have screen failed. This number does not count towards your enrolled subjects. Do not include them in the count for 4.0.
- 5. Item 6.0 Is the number of subjects who have completed all study related activities (if death is an endpoint in the study, those subjects who have died would be included in this number).
- 6. Item 7.0 Is the number of subjects who have withdrawn or been withdrawn by the PI from the study.
- 7. Item 8.0 is the number of subjects who have died unexpectedly.
- 8. Item 9.0 is the number of subjects who are still receiving treatment or intervention.
- 9. Item 10.0 is the number of subjects who are in follow-up.

There are also blue question marks with guidance information next to each item in the chart.

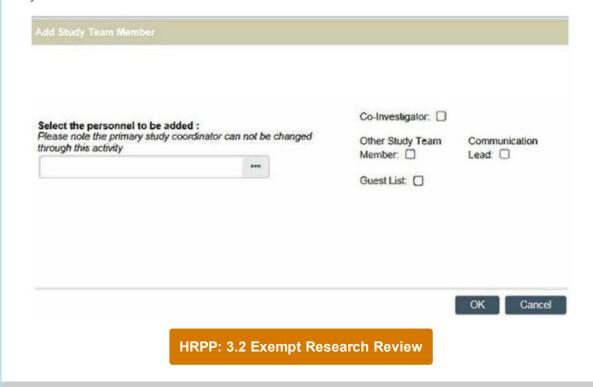
When considering these items and how they are reported in the chart, you always want to make sure that the numbers you report for Items 6.0, 7.0, 8.0, 9.0 and 10.0 add up to equal the number provided for 4.0 in Column C (the Cumulative Column). If the reported numbers do not add up, the IRB will return the CR to the PI for revision.

For more information on Continuing Reviews, please see the Continuing Review policy below.

HRPP: 3.5 Continuing Review and Annual Status Update Policy and Procedures

Exempt Studies – Add a Study Team Member Feature Reminder

The eIRB system has been modified to allow PIs and main study coordinators to add Co-Investigators and/or Other Study Team Members to Exempt studies without submitting an amendment. The PI or main study coordinator can also edit the Communication Lead or add to the Guest List. The eIRB system will automatically check the CITI training of the personnel being added. If the CITI training is not up to date, the system will not allow the person to be added to the study. Please note, this feature is available for Exempt studies only.



ClinCard for Subject Remuneration

If you are providing remuneration to study subjects and are considering using ClinCard, please keep in mind that you will find standard informed consent language available for use in the Suggested Consent Language Library on the IRB website. This verbiage is approved for use in the ICF's Payment to Participants section. You will also want to include you are using ClinCard in the Remuneration Smartform. For more information on ClinCard, please visit the Office of Clinical Research's (OCR) website below.

ClinCard Suggested Consent Language

OCR ClinCard

Office for Human Research Protections and Resources

The Office for Human Research Protections (OHRP) provides leadership in the protection of the rights, welfare, and wellbeing of human subjects involved in research conducted or supported by the U.S. Department of Health and Human Services (HHS). OHRP provides clarification and guidance, develops educational programs and materials, maintains regulatory oversight, and provides advice on ethical and regulatory issues in biomedical and behavioral research.

Please visit the OHRP website for many helpful resources when preparing your IRB applications.

Office for Human Research
Protections

Educational Resource for Researchers

Certificates of Confidentiality

Certificates of Confidentiality (CoCs) are issued by the National Institutes of Health (NIH) and other HHS agencies to protect identifiable research information from forced or compelled disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in civil, criminal, administrative, legislative, or other proceedings, whether federal, state, or local. CoCs may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects, such as damage to their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, CoCs help to minimize risks to subjects by adding an additional level of protection for maintaining confidentiality of private information.

Q: When do I use Certificate of Confidentiality information in my consent form?

A: If the NIH or other HHS agencies have issued a CoC for the study, only then would you include the CoC required language in the Informed Consent. The CoC language can be found on the IRB Suggested Consent Language website.

Certificate of Confidentiality Consent Language

eIRB Tip: Protocol Deviations

A protocol deviation is any variance from the protocol involving a subject or subjects that is not approved by the IRB prior to its initiation or implementation. Protocol deviations occur when a member of the study team departs from the IRB-approved protocol in any way without the investigator first obtaining IRB approval.

Tip: When submitting a reportable event for protocol deviation with the same variance from the protocol but includes multiple subjects, only one reportable event submission is needed, however, the report should include all affected subjects' study identification numbers for participants with the same deviation.

Similarly, if multiple protocol deviations have occurred with a single participant, one report can be filed to cover all of the deviations; when filling out the eIRB report form, remember to list all the deviations in the space provided.

HRPP 4.14: Protocol Deviation

About the Staff

Brea Roy

Brea Roy joined the IRB team in March 2023 as the IRB Coordinator for Board I. She started at MUSC in 2021. She earned her bachelor's in psychology from Coastal Carolina University and her Master's in Higher Education Administration from Northeastern University. In her spare time, Brea enjoys spending time with her family, reading, running, and going to Disney World as often as possible.

Contact Us

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

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