

Exempt Category 4 eIRB Application Tip Sheet

Responding to Reviewer Comments:

When responding to comments, please copy the comment, paste it in the response section, and then address or answer the comment.

****Please note:** When revising a document that has already been sent to the IRB in response to IRB comments, select the 'Upload Revision' button next to the document name and upload the clean *revised version*. **Please do NOT use the 'ADD' button to add the new document, or the 'DELETE' button** to remove the previous version. The IRB needs to have a history of revisions. This will allow us to see the changes made.

Study Identification Information Smartform:

3.0 – Scientific Rationale. The description/summary of the study should not be included here only the science behind why you are conducting this research.

4.0 - This should give a clear and concise description of the study and be written in lay terminology so that it can be easily understood by potential subjects. Explain the research procedures being done at MUSC (i.e. is this a chart review, etc.)

Reviewers should be able to know exactly what your study is about and what you are doing after reading this response.

Study Personnel Smartform:

4.0- Make sure everyone listed on the study is assigned a role and editing permissions.

eIRB Communication Coordinators Smartform:

1.0 - PI must be selected to receive communications. If applicable, the mentor listed on the application needs to be selected.

CITI

The application will not be approved until all study personnel have complete and up to date training.

If a study team member's CITI training has expired.

Option 1. Wait until the study team member completes their training and the updated training is showing in eIRB → return the study to the IRB

Option 2. Remove the study team member from the application → return the study to the IRB for review/approval. The study team member can then be added to the study after their training is complete, up to date, and showing as such in eIRB.

Exempt Category 4:

- 1.0 - Provide the IRB with the following information to justify the exemption:
 - List the data that will be recorded on the human subjects involved in the project (e.g., admission and discharge dates, diagnoses, medications, etc. (Also include any PHI elements needed to conduct the study: MRN, names, zip codes, etc. If radiologic imaging will be accessed, please add accession numbers to the list. Please also ensure the PHI listed here harmonizes with what is listed in questions 7.0 and 8.0 on the HIPAA Waiver of Authorization form, as well as the PHI selected on the PHI page.
- 2.0 - Where does the data and/or specimens currently exist? In the eIRB application, you will have the option to make the following selections. You will select all that apply:
 - o- medical records
 - o- existing databases or registries
 - o- Payment/Billing/Insurance Records
 - o- Outside entity/other Institutions
 - If applicable, list any outside sites where **MUSC involved** human subjects research will be performed and describe the role of those sites in performing the proposed research. If data will be sent or received outside of MUSC, describe how data will be transferred and whether the data will contain identifiers.
 - o- other (explain)
- 3.0 - Provide information about how the specimens, records, or data will be recorded
 - o- REDCap
 - o-Excel spreadsheet
 - o-other (please explain)

De-Identified vs Coded Data:

1.0 - Are you receiving any of the 18 PHI identifiers? If so, then the data would not be considered "de-identified". Data cannot be both de-identified and coded. If you are keeping a master list, please refer to data as coded.

Coding data is when you use a study identification number (random number) as a link between the data collection form and the master identification log. The identification log will contain a subject identifier.

The ID log and research data should be stored separately on MUSC secured network storage. This ID log can be deleted after data analysis.

Be sure that verbiage throughout the eIRB application reflect the correct terms based on the data you are collecting.

Privacy and Confidentiality Smartform:

1.0 - Include where your data will be stored and who will have access to the data. If coding data, include information on the use of a linking document that links the MRN to the study ID on your data collection database.

2.0 - Data should be stored on the MUSC network, not an end-use or portable device.

Please include the likely retention period (i.e. the linking document may be deleted after data analysis, and the study data will be maintained for six years per MUSC policy).

PHI Smartform:

1.0 - Select all elements of PHI that will be accessed, used, and/or recorded as part of your research.

As a reminder, in order to waive HIPAA, you should have the least number of identifiers needed to answer your research question.

Access to Protected Health Information (PHI) for Research:

1.0 – Where is your data coming from?

HIPAA Authorization Waiver:

1.0-This is addressing why the use of PHI involves no more than minimal risk to the privacy of individuals.

Who will have access to the data? Describe coding system if applicable and ensure that the linking document and the data will be stored separately.

Why are the risks reasonable in relation to the expected benefits and what is the knowledge to be gained from the results?

2.0 - Describe the coding system and ensure that the master code list will be kept separately from study data on MUSC secure network storage

3.0 - The ID log may be deleted after data analysis has been completed; however, the research data needs to be stored for a minimum of six years per MUSC policy.

4.0 - This section is actually requesting a statement that: “the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permissible”

5.0 - Include how it would be impracticable to obtain authorization from each subject since all data is in the medical record and some patients may be loss to follow up. Consider the fact that you will be attempting to contact a large number of patients and contact information recorded may be obsolete, data exists in medical records and was collected for clinical purposes and contacting patient to obtain authorization would increase loss of confidentiality, etc.

6.0 - Be sure to address HIPAA Waiver, not Consent. As a reminder, in order to waive HIPAA, you should have the least number of identifiers needed to answer your research question.

Explain why this study cannot be conducted without access to and use of PHI (i.e. PHI identifiers are needed to locate medical records, study data, and ensure subjects are not duplicated).

7.0 – The response should mirror all of the elements that you have selected on the Access to PHI for Research Smartform (MRN, address, email, etc). Please also ensure all PHI listed here harmonizes with the PHI listed in 1.0 on the Justification page.

8.0 - The question is asking why the PHI selected on the PHI Smartform is the minimum that you need to accomplish the study objectives. List each selection and describe exactly why those elements are needed.
Dates—please clarify why dates will be used (will they be used to calculate age, or will they be used to calculate treatment length, etc).

9.0 - The question is asking about the measures that will be put in place to protect the privacy since you are not obtaining authorization to use this information. Describe the use of a coding system, noting that the data will be stored on MUSC secure network storage and that access to the data will be limited to approved study team members. Please note that data currently exists in medical records and was collected for clinical purposes.

If additional assistance is needed. We highly recommend that you reach out to the SUCCESS center and take advantage of their **free regulatory assistance when submitting applications to the IRB. Consultations with the SUCCESS Center Team may be conducted via phone or video conference. These consultations are scheduled via a SPARC request. We find that those who take the time to reach out to them for a consultation session experience a more seamless submission and approval process. Their phone number is 792-8300 and their website for information on submitting a SPARC request is: <https://research.musc.edu/resources/sctr/about/success/regulatory>