Exempt Category 2 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. If there are study procedures, they should be included. Explain the research procedures being done at MUSC. 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 2:

1.0 - Provide the IRB with the following information to justify the exemption:

- Include information about the study population, the study setting, how participants will be identified and recruited; if you plan to use cold contact to recruit participants, see MUSC guidance at Cold Contact Recruitment Policy .
- For contacting patients: have the patients/subjects that are being called given permission to be contacted for future studies?
- If MUSC students and/or employees will be recruited, please address the measures that will be put in place to minimize coercion/undue influence.
- List the study procedure(s) in chronological order and include any remuneration that will be given for participation (if applicable).
- Describe any linkages to subjects (if applicable) and indicate who will have access to subject identities. If interviewing patients: Will the subject's interviews and MRNs be linked. If recruiting via email and interviewing those subjects: will those subject's interviews and email addresses be linked?
- For research studies that involve interviews/focus groups, please specify if the interviews/focus groups will be audio recorded. If they are being recorded, will they be transcribed? Will audio scripts be destroyed? Will the transcripts be coded?
- If applicable, list any collaborating sites where human subjects research will be performed, and describe the role of those sites in performing the proposed research. Describe how data will be transferred and whether the data will contain identifiers.
- For survey studies: Describe how the subject will accessing the survey.

2.0 – Supporting Documents:

- Upload an information paragraph that will be distributed to the participants prior to the completion of the survey, interview and/or focus group. The document should include the eIRB watermark. The information paragraph may include the following information:
    - Potential participants are being asked to participate in research study and that participation in research is voluntary
    - The purpose of the research who is conducting the research and why the participant is being asked to participate.
    - Include a statement on what (if any) identifying information will be stored. If any interview/focus group will be audio recorded.

- Instructions on how to return any completed surveys (if applicable), the duration of the study, how long each survey and/or focus group will take.
- Brief description of any risks (e.g. loss of confidentiality)
- Information about participant remuneration (if applicable).
- Information about who to contact if there are any questions.

Suggest beginning the paragraph with the following sentence: "*You are being asked to participate in this research study because you are [have] . . .*"

NOTE: If participants are being paid, the 1099 statement needs to be added: Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $2,000.00 in a calendar year, you will be issued a Form 1099.

NOTE: If students and/or employees are included, the following needs to be included:

Your participation is voluntary and your participation or discontinuance will not impact any element of your job or education performance/evaluation and will not become a part of your employment/education record.

NOTE: Recruitment materials should not be uploaded as supporting documents. These materials should be uploaded on the advertising/recruitment smartform. Recruitment materials should include an eIRB watermark.

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.

Recruitment Methods:

As a reminder, patients should be told about the research study by someone involved with their clinical care before they are approached by a member of the study team. If this is not the case, Cold Contact Recruitment is being used as the method of recruitment.

Application Checklist Smartform:

Selections often missed:

• Use of survey, questionnaire, focus group, interviews, group discussion

• Advertisements or recruiting materials: if any advertising will be used to recruit participants, this should be checked. Emails can be used to recruit participants.

• If calling subjects for recruitment: need to include opt out information in the telephone script (i.e. *If patient expresses desire to be opt-ed out from being contacted about any other research opportunities, please document that preference that on the Research Contact Form).

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.

Include if interview/questionnaire responses and MRN (or email addresses for those recruited via email) will be linked.

Include the likely retention period (the linking document can be destroyed after data analysis, and the research data will be stored for six years per MUSC policy).

Include information on recording interviews, and when the recordings will be transcribed. Will the recordings be destroyed, and if so, when.

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, to waive HIPAA, you should have the least number of identifiers needed to answer your research question.

For interviews: select 'biometric identifiers, including finger and voice prints'.

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 that 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. Suggest stating that 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).

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. If dates will be used: 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.