**Expedited 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. 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. - 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.

**Expedited Categories:**

If conducting a Chart Review, please select Category 5.

**Protocol:**

Please see the [Scientific Protocol Template (DOCX)](https://research.musc.edu/-/sm/research/resources/ori/irb/forms-files/scientific-protocol-template.ashx?la=en) from our website. While using the template it is not required, there is information that needs to be in the protocol per federal regulations. Using the MUSC Scientific Protocol Template is a useful tool to help ensure all elements of the protocol are included and helps IRB Administrators with their reviews. Thanks!

**NOTE:** What is included within each applicable section should harmonize with what is entered into each specific item within the eIRB application smartform (inclusion/exclusion, recruitment, risks, compensation, etc.).

Please be sure to spell out acronyms the first time they are used. Do not include names of individuals throughout the text or within the eIRB application, just include titles (i.e. PI, Study Coordinator, etc.) Also, the version and date need to be included in the header.

Inclusion / Exclusion:

As a reminder, exclusion criteria are applied to subjects who meet inclusion criteria. It is not appropriate to list opposites as exclusion criteria. There may be no exclusion criteria if inclusion criteria are met. Inclusion/Exclusion criteria should be listed separately and in bulleted format.

Risks:

For minimal risk research, all risks must be known and known to be minimal.  There cannot be any unforeseeable risks.

**Consent process:**

Please note that the consent process should take place in a private setting. Subjects should be given the opportunity to read the consent and ask questions before signing the consent. Also note that the subject will be given a copy of the signed and dated consent.

No research procedures can be performed prior to consent.

Consenting is not a research procedure.

**Study Subjects**

If recruitment of students and employees and disadvantaged is just incidental and they are not a targeted group, then do not make those selections Also, applicable sections are not required in the Informed Consent Form.

**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.

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.

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

**PHI Smartform:**

1.0 - Select all elements of PHI that will be accessed, used, and/or recorded as part of your research. (This includes PHI needed for chart review to determine eligibility, and PHI required to distribute remuneration)

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.

\*\*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