Submitting a Cold-Contact Recruitment Plan to the IRB

Outlined below is best-practice guidance for what to include in IRB applications when the intent is to use cold-contact as a recruitment method for the study. Bolded text is the eIRB application page that the specific guidance is applicable to. This information is specific to the cold-contact aspect of your study and is not inclusive of all of the information that needs to be included about your study in an IRB submission. Also, please note that this cold-contact process is specific to recruiting MUSC patients.

<u>New Expedited/Full Board IRB Submissions</u>

- **Study Protocol**

  2.0- Please be sure that the following is included in your uploaded protocol document

  - *Inclusion/Exclusion criteria* section should be consistent with how you intend to identify patients to be included on your recruitment report
  - *Recruitment Methods* section should include that you will be submitting a Research Data Request to obtain a recruitment report of MUSC patients who potentially meet eligibility criteria. State that the study team will not cold-contact any patients who have opt-ed out of receiving contact about research. Include what method(s) of contact you plan to use to contact the participant
  - *Data Management* section should specify that recruitment projects are housed in REDCap and include a discussion of who will have access to the recruitment project database. State that the research team will only have access to the REDCap recruitment project while actively enrolling for the study. If you plan to use REDCap to store your research data, be sure to distinguish that this recruitment project will be stored separately from the project containing your research data.

  For Industry sponsored studies or studies relying on an external IRB, where creating local protocol is not feasible, please include the below information on the applicable eIRB application pages instead

- **Study Populations-Study Subjects**
  - 8.0
    - Harmonized with your protocol, this criterion should be consistent with how you intend to identify patients to be included on your recruitment report

- 9.0
    - Include that you plan to utilize a cold-contact method as part of your recruitment plan. State that you will be submitting a Research Data Request to obtain a recruitment report of MUSC patients who potentially meet eligibility criteria. Include confirmation that the study team will not cold-contact any patients who have opted out of receiving contact about research. Also include what method(s) of contact you plan to use to contact the participant

- **Checklist-Application Checklist**
    - 1.0
        - Select "Medical Record, Chart Review" to account for the contact information and any additional patient info you will receive on the recruitment report
        - Select "Advertising or Recruiting Materials" to capture the phone script that will be utilized as the method of cold-calling

- **Other Study Specifics-Advertisements**
    - 1.0
        - If planning to use phone calls, emails, or MyChart messages, check "Other"
        - If planning to mail letters to a specific address, check "direct mailing
    - 2.0
        - Explain how you will execute the mode(s) of recruitment (E.g. the cold-calling script will be utilized to contact patients by phone; the MyChart message will be used to message participants)
    - 3.0
        - If you plan to utilize phone calls as your method of contact, upload MUSC's Cold-Calling script template
            - In 2.0 of the script please insert language about the research topic and, a lay friendly description what criteria was used to identify these patients
                - "***This particular study is about*** *[insert research topic]****, so we are contacting patients who*** *[provide primary inclusion criteria (e.g., have high blood pressure, have received a positive COVID-19 test)]*."

- In 3.0 of the script please insert a lay friendly description of the study and a brief overview of what the study involves
- Be sure to include the MUSC eIRB watermark (found on the IRB's "Forms" page), at the bottom of the template, as the IRB must stamp this document for approval

- If you plan to utilize messaging/direct mail please upload a template of your message/letter
  - In this messaging/letter be sure to include why the patient is being contacted, how you got their contact information and way for the patient to obtain more information about the study if he/she is interested
    - Example: Because MUSC is a research hospital, and we always want to give patients the opportunity to participate in studies when they are able to, our researchers are allowed to look at health records to find patients to contact that might be good fit. This particular study is about [insert research topic], so we are contacting patients who [provide primary inclusion criteria (e.g., have high blood pressure, have received a positive COVID-19 test)].

    Be sure to include the MUSC eIRB watermark (found on the IRB's "Forms" page) at the bottom of the message/letter, as the IRB must stamp this document for approval

- **Consent Process-Consent Process Part 1** (for teams using MyChart Messaging)
  - 7.0
    - If you plan to use MyChart to send recruitment messages, you must include the following in Section E. "MEDICAL RECORDS AND/OR CERTIFICATE OF CONFIDENTIALITY" of the informed consent:

"If you are an MUSC patient you have an MUSC medical record. If you have never been an MUSC patient, a MUSC medical record will be created for the purposes of this study. Documentation of your participation in this study will be included in the medical record and results of research tests or procedures may be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep confidential all research information in the medical record that identify you to the extent allowed by law."

- **Privacy-Privacy and Confidentiality**
  - 1.0
    - Indicate that the recruitment report will be stored as a project in REDCap and who will have access to it
      - If you plan to use REDCap to store your research data as well, please clearly distinguish between the research vs. recruitment database and indicate that they will be stored as two separate projects.
    - State that the study team will lose access to the recruitment project at the conclusion of enrollment
    - Please note, this recruitment REDCap project will potentially contain both identifiers and health information in the same project, and if so, you will need to be transparent about that in this section
  - 2.0
    - Check "Password protected network storage" to account for the REDCap recruitment project.

- **Privacy-Protected Health Information (PHI) For Research**
  - 1.0
    - Check "name" so you can address the participant
    - Check any other PHI required for the type of contact you plan to utilize (E.g. phone number for calling, address for mailing)

- **Privacy-Access to Protected Health Information (PHI) for Research Purposes**
  - 1.0
    - Check "Medical Records/Physician Notes/Hospital Discharge Records" to account for information included in the recruitment report
  - 2.0
    - Check "HIPAA Waiver of Authorization for Research" to account for viewing/utilizing the PHI included in the recruitment report prior to participant knowledge/consent
- **Privacy-HIPAA Waiver of Authorization for Research**
  - 2.0
    - Acknowledge that PHI provided in the recruitment report will be stored in REDCap and that only IRB approved personnel will have access to that data.
  - 3.0
    - Explain that the study team will no longer have access to the redcap recruitment database after enrollment for the study has concluded
  - 5.0
    - Explain why you would not necessarily have access to recruit these participants in person, and consequently how you would need the HIPAA waiver to obtain the contact information necessary to employ the recruitment methods necessary to the enrollment goals of the project

- 6.0
  - State that you need to be able to view/utilize the patient's PHI in order to get the contact information needed to recruit participants for the study
- 7.0
  - Include the list of identifiers you plan to receive in your recruitment report
- 8.0
  - Justify that the PHI included in your recruitment report is the minimum required to identify potentially eligible patients and contact them for recruitment purposes
- 9.0
  - Include if you have the intent to obtain verbal/written HIPPA from the participant should they agree to participate in the study prior to collecting any additional information.