

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. The 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.

Important Note: Please do not duplicate any information or document uploads specific to cold-contact in any areas other than the cold-contact smart form.

New Expedited/Full Board IRB Submissions

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 opted out of receiving contact about research. Include what method(s) of contact you plan to use to contact the participant.

Important Note: For studies involving youth populations, please use the following guidelines:

- For youth 16 years of age and older study teams are permitted to approach the potential participant via MyChart but must obtain parental permission to participate.
 - For youth younger than 16 years of age study teams must reach out to the potential participant through the parent or guardian.
- *Data Management* section should specify that recruitment reports will be delivered by an honest broker through a secure data delivery method. Include a discussion of who will have access to the recruitment project database. State

that the research team will only have access to the recruitment report while actively enrolling for the study. Be sure to distinguish that any recruitment reports that will be delivered will be stored separately from any projects containing your research data.

Important Note: Prior to engaging any 3rd party recruitment vendors, you must contact the POR Team. Studies using 3rd party recruitment report resources may be required to include additional specific language about report delivery and utilization.

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.

Study Population–Cold Contact

- 1.0
 - Explain and describe all methods that will be used to cold contact patients that appear on the recruitment report.
- 2.0
 - Explain why cold-contact is an appropriate recruitment strategy for the protocol.
- 3.0
 - Select what method(s) of contact you plan to use to contact the participant
- 4.0

- Upload applicable cold-contact recruitment scripts for use by telephone, MyChart® and/or direct mailing.
 - 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

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)].
- **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
 - Advertising/recruiting materials should only be checked to capture materials being used for recruitment materials OTHER THAN the cold-contact methods (Which have been previously captured on the cold-contact smart form page).

- **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. This section should only address study-specific advertisements that occur outside of the cold-contact method of recruitment.

Important Reminder: Please do not duplicate any uploads or detail any information already captured on the cold-contact page. Studies using ONLY cold-contact and no other method of recruitment should not select anything in this section.

- **Privacy-Privacy and Confidentiality**

- 1.0

- Indicate that the recruitment report will be delivered by an honest broker through a secure data delivery method. Include a discussion of who will have access to it.
 - Be sure to distinguish that any recruitment reports that will be delivered will be stored separately from any projects containing your research data.
 - State that the study team will lose access to the recruitment project at the conclusion of enrollment.
 - Please note, this recruitment report 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 recruitment report being delivered through a secure data delivery method.

- **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 the information included in the recruitment report.
 - 2.0
 - POR reports that include PHI that will ONLY be used for the purposes of recruitment and NOT maintained as part of the research data set, fall under "Accessing Information for Preparatory Work for Research". If the report includes PHI that you intend to maintain as part of your research data, then you will need to select "HIPAA Waiver of Authorization for Research" instead. Please note, other items on this list may also need to be selected if they apply to your study. This guidance only pertains to the selections that apply as a result of your use of POR.

The remainder of the application should be completed as it pertains to the rest of the study procedures