



I. Introduction

The policy applies to all research recruitment activities by MUSC researchers. The IRB will evaluate the selection and recruitment of research participants in accordance with all relevant laws and regulations.

Recruitment is considered the start of the participant selection process and is a prelude to the informed consent/assent process. Investigators and the IRB must respect an individual's reasonable expectation for privacy when considering how information is gathered about a potential participant and who will invite the individual to participate in the research. Investigators and the IRB must also ensure that recruitment activities are free of bias, do not exert undue influence on or coerce a potential participant to volunteer, or imply a guarantee of benefits beyond what is outlined in the protocol and consent form approved by the IRB.

II. Policy

Recruitment methods used to solicit volunteers into human research must be equitable and free of bias, undue influence and coercion and must respect the privacy of potential research participants. The IRB must review and approve the methods, materials, procedures, and tools used to recruit potential research participants before they are implemented.

A. Screening, Recruiting, or Determining Eligibility (45 CFR 46.116(g))

An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject's legally authorized representative, if either of the following conditions are met:

- (1) The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or
- 2) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens

B. Contacting Prospective Participants Who Were Identified From Medical Records

In general, the IRB does not approve of “cold calling” patients about potential research opportunities. Cold calling is when an individual is contacted by someone they do not know and the contact is unexpected.

When the participant’s clinician is also the Principal Investigator for a study, the PI may approach a patient directly about participation in any of the PI’s IRB approved research trials. The PI’s personnel may also approach the patient and provide information about the research study.

PIs or research staff, who are not directly involved in a patient’s clinical care, may NOT contact that patient regarding research participation without the patient’s permission.

The research team may request that a clinician present his/her patient with information about the opportunity to participate in research. The clinician may directly (e.g. during an office visit) or indirectly (e.g. by letter, email, flyer) provide information about the research study, and/or provide a contact number for the PI or research staff to the patient. Study information provided by a clinician should not include any language or information that may be perceived as unduly influencing or coercive, or imply that medical care could be influenced by choice to participate or not. If the patient is interested in the research study, then he/she contacts the research team for more information. Patient information may be released to the PI or research staff only if a potential participant gives permission for his/her identifying information to be shared.

One way in which a patient may give permission to be contacted about a research study would be by agreeing to be contacted for research through the MUSC electronic health record (e.g. via MyChart). In this instance the PI/research team may directly contact patients who have agreed to be contacted for research. This method must be discussed in IRB application and must be approved by the IRB.

C. Opting In Versus Opting Out of Research

Opt-in: Researchers using this method contact potential subjects, usually with a recruitment letter, and ask them to get in touch with study staff if they wish to learn more about a research study. The investigators must then wait for subjects to contact them. The Opt-in method is more respectful and presents less risk of annoying potential subjects because they only contact the researchers if they are interested in the study. Opt-in recruitment is less popular with investigators since they must passively wait to be contacted by

potential subjects, who might not initiate contact even though they might be interested in participating.

Opt-out: Researchers using this method contact potential subjects with a recruitment letter informing them about the existence of a research study. Individuals are told that they will be contacted by the researchers *unless* they call or mail back a card indicating that they are not interested (opt-out). Potential subjects could potentially be annoyed or offended by this approach since they have less choice in deciding whether or not to learn more about the research because they must make an effort to opt out. At the same time, this method is more feasible for investigators, particularly if subjects are difficult to contact or belong to a group that typically does not actively volunteer for research studies. As a rule, many subjects who might be willing to participate don't make the effort to opt-in so by using the opt-out approach these subjects may be contacted and may agree to participate.

The IRB may approve opt-out methods of recruitment if:

- The researchers provide justification in the IRB application as to why this strategy is appropriate
- The research does not involve very sensitive information (e.g., questions about illicit drug use, sexually transmitted diseases, alcohol abuse, emotional and/or mental disorders) – if it does the investigator must explain in the IRB application how this can be done without offending potential subjects
- The recruitment letter gives the potential participant clear instructions about how to opt out and offers **preferably two ways of opting out** (e.g., mail, phone, email)
- When individuals who did not opt out are contacted, they are reminded that they were sent a letter and are told at the start of the call that they can still “opt out now”
- The number of times the investigator will attempt to contact subjects who do NOT opt-out is limited (usually to three attempts). Making a large number of attempts to contact subjects trying to get them to participate could be viewed by the general public as harassment.

C. Secondary Recruitment

Secondary recruitment methods are used when investigators wish to recruit specific groups of participants through friends and family of existing participants. Some forms of this type recruitment are often called "snowball" recruiting. To protect the privacy of those being recruited, the IRB carefully considers whether these methods are appropriate for a given study.

Participant-initiated Secondary Recruitment is when the researcher asks current subjects to pass along recruitment materials or information to friends and family. The participant initiates the contact with family and friends, and these people must then contact the researcher if they wish to learn more about the study. This method is generally acceptable to the IRB.

Payment for Secondary Recruitment. It is permissible to allow this form of recruitment for studies by providing cash, gift certificates or other incentives to subjects to promote their aid in recruiting new individual subjects into studies. Such practices are allowable. The incentive to any subject should be picked with moderation, with justice and autonomy being considered. The level or amount of the incentive should be based on current local norms and must be approved by the IRB.

Modified Snowball Recruitment is when investigators ask participants if they have family and friends who might be eligible and interested in participating in the research. The investigators only get in touch with these secondary contacts AFTER the subject has confirmed that he/she has obtained permission from the family members/friends to have the researchers contact them.

D. Future Recontact

During the consent process, investigators may ask potential participants if they would be willing to be recontacted for future research studies. The response to this should be documented in the informed consent. It is then permissible for the investigator to include the name and contact information of that individual for future studies. This list of individuals who are willing to be contacted for research purposes should not be stored with health information.

E. Research Involving MUSC Employees or MUSC Students

For specific guidance see HRPP 8.6 Research Involving MUSC Employees and Students

F. Recruitment Materials

For specific guidance see HRPP 7.2 - Advertisements for Research Participants Policy and Procedures

G. Finders Fees

The MUSC IRB does not allow the use of finders' fees in research. For specific guidance see HRPP 7.4 – Recruitment Incentives Policy and Procedures.