

PPHS Guidance on Recruiting Subjects for Research

SECTION I: Guidance on Recruiting Peers, Colleagues and/or Individuals in a Subordinate Role (students, employees) to Research

I. Background

Federal regulations at 45 CFR 46.111(a)(3) task the IRB with being “particularly cognizant” of subjects who may be vulnerable to coercion or undue influence. When studies involve people who may be vulnerable in these ways, researchers are responsible for adding safeguards to protect subject rights and welfare [45 CFR 46.111(b)]. This guidance discusses the ethical issues involved with the use of peers, colleagues and persons in subordinate roles when deemed scientifically necessary and the requirement for IRB approval prior to enrolling subordinates.

II. Scope

This guidance applies to any recruitment plans for research conducted at, or overseen by, a site within The Mount Sinai Health System.

III. Guidance

Peers, colleagues and subordinates, such as students or employees, may experience a sense of coercion or undue influence, to enroll in a study that is being conducted by an instructor, employer or service provider. The real or perceived sense of pressure will be higher when supervisors or instructors invite those in a subordinate role to participate, as they may either find it difficult to say no or they may choose to participate to gain favor or benefit. Even peers and colleagues working together (i.e. without one being in a subordinate role) may find that there is still enough peer pressure and socialized expectations that it is difficult to freely give or withhold consent. Therefore, it is imperative that investigators are particularly cognizant of imbalances of power and social expectations that may exist between themselves and the potential subjects they approach for research.

Unless the IRB agrees with the investigator’s assertion that it is scientifically necessary, individuals who would be considered vulnerable to coercion or undue influence, such as peers, colleagues and people in a subordinate role, should not be enrolled. For situations deemed to be scientifically necessary, IRB approval must be obtained for their inclusion in the research and their inclusion in the research must be specifically mentioned in the protocol/HRP-503. Additional protections to safeguard the rights of these subjects must be presented and approved by the IRB prior to their enrollment in the research.

SECTION II: Guidance on Recruiting Patients to Research within the Mount Sinai Health System

I. Background

Recruitment from the patient population of the hospitals within the Mount Sinai Health System is common. Recruiting from one's own patient population is typically allowed as appropriate; recruitment of individuals seeking clinical care from other providers at the hospital is acceptable only when certain steps are taken to ensure the privacy and confidentiality expectations of patients are met.

In the setting where an investigator proposes to recruit other providers' patients, the IRBs of the Mount Sinai Health System provide guidance to the investigator regarding the necessary steps to be taken.

II. Scope

This guidance applies to any patient recruitment plans for research conducted at, or overseen by, a site within The Mount Sinai Health System.

III. Guidance

Recruitment by investigators making a "cold contact" with potential research subjects who receive medical care within Mount Sinai Health System is generally not approved. A "cold contact" in this setting is defined as a planned contact/communication (such as a face-to-face contact, telephone call, letter, or email) with a potential research subject by the investigator or a member of the research team when neither the investigator nor the contacting person is known to the potential subject as having a reason to know his/her medical diagnosis or other identifiable private information such as protected health information (PHI).

Conversely, if a caregiver or clinical care team is known to the patient as having reason to know his/her medical diagnosis or other PHI and agrees to make contact with the patient seeking his/her research participation, or seeking an expression of his/her interest in learning more about possible research participation, this would not be regarded as a "cold contact". The clinical care team is not limited to a treating clinician but may include other providers or care givers who are part of the same clinical team who would reasonably be expected to care for the potential subject outside of the research protocol.

- For studies involving direct contact from other members of the clinical care team, the PI should describe who from the clinical care team (including their title/role in the care) will be contacting the potential subjects.

When recruitment plans involving patients not under the clinical care of the PI or research team of the research study, the following steps should be taken to ensure the reasonable privacy expectations of Health System patients are considered:

1. Provide IRB-approved study information (brief) to the patient's physician or primary care provider.
2. Obtain permission of the patient's Mount Sinai Health System physician to contact the potential subject. If the patient is not currently receiving care within Mount Sinai Health System, the permission would be requested from the person's primary care provider.
3. Only contact potential subjects when informed by the clinical care team that contact is permitted.

Methods of obtaining permission to be contacted through opt-in approach:

An introduction to the study may be made by the caregiver in person during a hospital or clinic visit. In order to “opt-in,” the physician, primary care provider or other caregiver provides the patient with an introduction to the study and the name of the investigator or research team who will contact the patient. The patient must express interest in the study and agree to be contacted before the investigator can contact the patient. If the patient does not agree to be contacted or declines, the patient must not be contacted by the investigator. Since the clinical care team must first broach the subject of recruitment with the patient, the clinical care team must communicate to the Investigator which patients can/cannot be contacted before the Investigator initiates any contact with the potential subject.

Alternatively, an introduction to the study may be made via a letter to the patient from the physician or other appropriate caregiver or clinical care team. This letter must come from the physician, caregiver or clinical team member but may also contain the investigator name and contact information. If a letter is to be used, it should contain the telephone number the patient may call to receive more information about the study and to initiate contact with the study. The patient must initiate contact or agree to be contacted by the investigator. If the patient does not “opt in” or initiate contact with the investigator, no further research contact should occur.

In some cases, the IRB may grant the request of a researcher for an opt-out approach rather than the preferred opt-in. In this case, the potential subject must be provided with the telephone number and name of a study contact person that the potential subject can call to decline further contact related to the study. The opt-out approach must be approved by the IRB. Reasons for requesting an opt-out rather than opt-in approach must be explained and justified by the investigator and approved by the IRB.

Methods of communication with potential subjects through the opt-out approach: In this situation, an introduction to the study may be made by the caregiver in person during a hospital or clinic visit. The physician, primary care provider or other clinical care team member provides the patient with an introduction to the study and the name of the investigator or research team who will contact the patient. In the absence of a patient’s objection, the investigator can contact the patient. If the patient does not agree to be contacted, declines, or expresses no interest, the patient must not be contacted by the investigator. Since the clinical care team must first broach the subject of recruitment with the patient, the clinical care team must communicate to the Investigator which patients can/cannot be contacted before the Investigator initiates any contact with the potential subject.

Alternatively, an introduction to the study may be made via a letter to the patient from the physician or other appropriate clinical care team member. If a letter is to be used, it should contain the telephone number the patient may call to receive more information about the study if he/she needs this to decide whether to permit initial contact by the study team. If a letter is to be used, it should contain the telephone number the patient may call to “opt-out” or decline to be contacted by the investigator or research team. The letter should state the number of days the subject has to decline to be contacted and that a second notice will be sent. At a minimum, subjects should have 10 days to decline to be contacted and a second letter with similar information should be sent no sooner than 5 days after the first. If the subject contacts the research team and declines to be contact, the investigator and research team must not contact the patient. In the absence of a patient refusal to be contacted, the investigator or research team must wait at least 10 days before contacting the patient. The investigator or research team can only attempt to call the contact number(s) he/she has for the potential subject if the potential subject has not declined. The investigator/research team should plan on



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no more than two phone calls per contact number to establish contact.