
Yale University Institutional Review Boards Procedure

Procedure 410 PR.1 Who May Contact Eligible Participants

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Overview

This procedure describes how individuals may be directly recruited for involving in research. Prospective research participants should be contacted by persons generally known to them such as persons directly involved in their care and not by unknown researchers.

Who May Recruit Potential Research Participants:

Persons initiating contact with potential participants, either in person or by phone, must have sufficient knowledge of the study to answer questions. They must also be knowledgeable of where to refer a potential participant should questions be raised about the research participant's rights.

The following ethical concerns should be evaluated when considering recruitment strategies for research.

Exceptions:

Research investigators may seek approval from the IRB to contact the potential participant directly. However, such approval will only be granted when the IRB considers it impracticable to contact participants through an individual known to them.

Ethical Considerations:

The following topics should be considered in designing a direct recruitment strategy to protect the prospective participants privacy as well as to ensure that the prospective participants understand both the research nature of the invitation as well as the voluntary nature of participation:

- **The "Therapeutic Misconception:"**

Potential research participants who are also patients may believe that a clinical trial proposed by their health care providers will provide a therapeutic benefit to them, even after being told that there is no assured benefit. Therefore researchers and IRB reviewers should consider whether or not the recruitment strategy functions to counteract this misconception. Health care providers, who are inviting one of their own patients to participate in a research study conducted by a colleague must also be mindful of the same "therapeutic misconception".

- **Conflicting Concerns:**

- Potential research participants may prefer that someone involved in their care contact them about research, but they may find it hard to say "no" to a care provider.
 - Clinicians may find their clinical judgment in conflict with a desire to enroll patients in their research.

- **Undue Influence:**

Recruitment methods must also acknowledge that invitations to participate by individuals who hold a potential power relationship with the prospective participant (eg health care

provider/patient, faculty member/student, supervisor/employee) may create difficulty in declining the invitation to participate in research because they may still believe the research to have benefit because it was offered by their provider, instructor or supervisor. Additionally, some prospective participants may have difficulty declining because they simply want to please their provider/instructor/supervisor. Recruitment methods and activities must be conducted to assure the potential participant that his/her medical treatment, job, promotion, grade, etc., are not dependent upon their participation.

Recruitment and HIPAA Privacy

For purposes of recruitment, people are considered “involved in the patient's care” (and therefore eligible to review HIPAA-protected information without an authorization or waiver) if they are (1) health care professionals actually involved in the care or (2) administrative or research staff working with the professionals involved in the care.

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