
Yale University Institutional Review Boards

IRB Policy 410 Recruitment of Research Participants

Responsible Office	Office of Research Administration	Effective Date 1/7/09
Responsible Official	Institutional Review Board Executive Chair	Last Revised 8/20/12

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Scope

This policy ensures the equitable recruitment of potential research participants by providing information regarding appropriate methods and mechanisms for recruiting research volunteers. This policy applies to all investigators at Yale or its Research Affiliates who conduct recruitment activities for University human research.

Policy Statement

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 Institutional Review Board (IRB) must review and approve the methods, materials, procedures, and tools used to recruit potential research participants before they are implemented.

Reason for the Policy

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.

Definitions

Advertisements

Direct - Flyers, notices, posters, radio/TV spots, press releases, newspaper advertisements, signs, brochures, internet postings, etc. that are intended to attract potential participants into research studies.

Media – newspaper, TV, radio, websites

Bias

Show favoritism for or prejudice against (someone or something) unfairly.

Coercion

The act of using force or threats, whether actual, implied, perceived or indirect, to encourage an individual to participate in a research study.

Convenience Sample

Convenience sampling selects a particular group of people based on aspects of the potential participant's situation which renders them more easily accessed by the investigator or more likely to complete research participation without regard for the representativeness of the sample. Convenience sampling does not come close to sampling all of a population or a representative sample of a population. Convenience sampling may unfairly expose a population to research related risks.

Exculpatory Language

Language that waives or appears to waive any of an individual's legal rights or which releases or appears to release the investigator, sponsor, the institution or its agents from liability for negligence.

FERPA

Family Educational Rights and Privacy Act. A Federal law that protects the privacy of education records of students. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.

Health Care Provider

A person considered to be engaged in the patient's medical care.

HIPAA

Health Insurance Portability and Accountability Act of 1996. HIPAA (45 CFR §160, §162 and §164) establishes security and privacy standards for the use and disclosure of "protected health information" (PHI).

Newsletter

A written release, usually issued periodically, prepared by a sponsor or investigator, with the intent to inform subjects and/or investigators about the progress of the study or share other relevant information regarding the research or the condition being studied.

Press Release –

In general, a press release is a non-study-specific communication and does not require IRB review and approval if the information contains:

- generic information identifying a number of disease-specific studies
- an announcement to the general community inspiring interests to become prospective participants, for example, "*For studies available in the Department of Neurology please contact the general information number*" or "information on cancer trials available at Yale Cancer Center please contact the main line at XXX-XXX-XXXX."

The press release should not list the name of the investigator, research coordinator, name of study, eligibility criteria, subject incentive payments or specific contact information.

Privacy

In the context of research, privacy refers to an individual's right to control access to personal information about him or herself.

Script

A written description that indicates the general research plan or procedure that will be communicated to potential participants.

Snowball Sampling

In ethnographic and [statistics](#) research, snowball sampling (or chain sampling, chain-referral sampling, referral sampling) is a [non-probability sampling](#) technique where existing study subjects recruit or refer future subjects from among their acquaintances.

Therapeutic Misconception

The belief that a research study is intended to benefit the participant who enrolls in it and that an individual is asked to participate in a research trial as part of his or her routine care.

Undue Influence

The inappropriate use of prestige, wealth, ability or position to directly or indirectly affect the potential participants' decision to participate.

Policy Sections

410.1 Methods of Recruitment

All recruitment methods must be thoroughly described in the protocol. The investigator must carefully consider the targeted research population, study aim, participant privacy, and potential for bias and influence when designing recruitment activities for specific protocols. For example, health care providers who also serve as researchers and wish to enroll their patients into research must ensure that recruitment methods do not inappropriately promise or suggest therapeutic benefit to the patient beyond what is written in the protocol and consent form as a means to entice their participation.

The following methods of recruiting research volunteers may be approved by the IRB where appropriate:

A. Advertisements

Materials or methods used to recruit volunteers into human research studies must be submitted to an IRB for review. The IRB must review and approve the final copy of all advertisements including printed material, newsletters used for recruitment purposes, internet advertisements and telephone, email, video and audio scripts. Such materials may not be used prior to IRB approval.

Advertisements should be submitted to the IRB at the time the investigator is submitting the initial protocol. Should an investigator decide at a later date to advertise for participants using a different recruitment method, the advertisement must be submitted to the IRB as an amendment to the protocol. Likewise, any changes to the currently approved recruitment documents must be formally submitted to the IRB as an amendment request.

B. Identification of Potential Participants Through Existing Data (e.g., Clinical Records and School Records)

Yale IRB review and approval is required in addition to the review and approval from sources holding existing data prior to a research team member reviewing existing data sets for the identification of individuals who may be eligible to participate. (Examples: Yale New Haven Hospital (YNHH) Medical Records, Yale Medical Group (YMG) medical or billing records, student academic records and Yale Pathology records, etc.) Data sources that are not publicly available may be subject to additional institutional or regulatory requirements prior to access, such as the Family Educational Rights and Privacy Act of 1974 (FERPA or the Buckley Amendment) and HIPAA requirements. Access to such data will be approved by the IRB only when the proposed recruitment plan is compliant with these additional requirements, such as HIPAA waivers of authorization (45 CFR §164.512(i)(1)) or limiting access to only those data elements allowable under FERPA.

Persons who have been identified as possibly qualifying for a research project without their knowledge should be initially contacted by an individual known to the potential participant. For example, persons identified through a clinical record review should be contacted via their treating clinician or other health care provider or students identified through their academic record should be contacted by school personnel.

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 for investigators to have potential participants contacted by an individual known to them.

C. Use of Third Party for Recruitment of Potential Subjects

Yale IRB review and approval is required when a third party is used to inform potential subjects of a research opportunity. Examples of a third party would include community physicians or school administrators who are asked to provide their patients or students with information regarding a research study. Third parties may also include commercial entities hired to aid in recruiting research volunteers.

IRB review and approval is also required of all materials used by the third party to inform potential research participants of the study, such as “Dear Colleague” or “Dear Patient” letters.

Third party recruiters may provide the research contact information directly to the potential participant. The collection of additional research-related information used to determine eligibility cannot be conducted by the third party.

The use of currently enrolled research participants to recruit additional research participants (sometimes referred to as “the snowball sampling”) may be approved by the IRB provided that certain conditions are met. Specifically, current participants who do not receive rewards for referral or any rewards are generally determined by the IRB to be unlikely to induce bias, coercion and undue influence and such rewards do not adversely impact the confidentiality and privacy of future participants.

D. Development and Use of Recruiting Lists and Registries

Investigators may create and maintain lists of research participants who previously took part in, were screened for but deemed ineligible for other research studies or who have expressed interest in future research participation. In each of these scenarios, the individual must provide consent for their name to be retained for recruitment for future research participation. The development of such a recruitment list requires IRB approval. The IRB must ensure the appropriateness of the data elements to be maintained on the individuals as well as the confidentiality and security measures associated with the data set. Investigators may contact individuals on IRB-approved recruiting lists directly for future research consideration. Investigators must provide such individuals the opportunity to remove their name and any information from the list at any time.

Use of registries such as the Yale Center for Clinical Investigation (YCCI) subject recruitment registry must be indicated on the IRB application. The use of federally funded clinical trial registries (Clinicaltrials.Gov) is not considered by Yale to be a recruitment method requiring IRB approval. Therefore, copies of the information posted on Clinicaltrials.Gov need not be attached to the protocol being submitted to the IRB.

410.2 Requirements for Direct Contact with Potential Participants

Researchers and study personnel 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 about where to refer a potential research participant should questions be raised by him or her about their research rights.

A. Recruitment of Patients

Health care providers who are inviting one of their own patients to participate in a research study conducted by themselves or a colleague must be mindful of and minimize the potential for therapeutic misconception or coercion.

B. Recruitment of Students and Staff

Researchers wishing to recruit their own students or staff to participate in research must ensure that the recruitment plan minimizes any perception of coercion or undue influence. The recruitment plan must assure the potential participant that his/her job, promotion, grade, etc., is not dependent upon their participation. Please refer to IRB Policy 350 – Participation of Yale Students and Employees in Research for additional considerations.

410.3 Recruitment Time Frames and Settings

Recruitment activities must be designed and conducted in a manner that permits potential participants sufficient time, determined by the nature and risks of the research, to consider whether or not they wish to participate. In approving a recruitment plan, the IRB will consider the proximity in time of the recruitment, informed consent process and research interventions so as to assure clear decision making and the avoidance of undue pressure or excessive inducements. Recruitment activities must be carried out in a setting that provides privacy to the potential participants and that is free of situational or environmental influences or intimidations.

410.4 Monetary Incentives and Bonuses

Researchers are prohibited from using the amount of payment and/or the proposed method and timing of the disbursement of the payment in a manner that may be perceived as unduly influential.

University researchers and staff are prohibited from receiving or dispersing bonuses or incentives for recruitment, referral or enrollment, except as described in section 1C above.

410.5 IRB Review and Approval of Recruitment Procedures

The IRB is required to ensure and will approve research recruitment methods that: 1) are appropriate for the type of research being proposed; 2) are free of bias, coercion and undue influence; 3) do not make false or misleading claims about the study or the benefit to the research participant, and 4) do not contain exculpatory language.

410.6 Press Releases (Announcement, Bulletin, News Release, etc.) and IRB Approval

Researchers who wish to submit a press release may do so without IRB approval as long as the information contained in the document does not include the following:

- Name of the specific study
- Eligibility – inclusion and exclusion criteria
- Investigator or specific research study personnel
- Sponsor of the study
- Payment information (compensation/reimbursement) for participation
- Specific contact information (name, telephone number, etc.)

Special Situations/Exceptions

Study newsletters

Study newsletters that are created with the intent to recruit subjects require prior IRB review and approval. General study newsletters that are not distributed as recruitment materials do not require individual review. The intent to use and the expected content of the newsletters need to be described in the protocol application and approved by the IRB, but continuing IRB review and approval of issued newsletters is not required if their purpose is informational only.

Related Information

- [410 PR 1: Who May Contact Research Participants](#)
 - [410 PR 2: Recruitment Time Frames and Settings](#)
 - [410 PR 3: Advertisements, Notices and Scripts Used for Recruitment](#)
 - [410 GD.1: Guidelines on Posting for Recruitment](#)
 - [410 GD.2: Guidance on Phone Screening](#)
 - [IRB Policy 350: Participation of Yale Students and Employees in Research](#)
 - [350 CH 1: Checklist for Research Studies Involving Yale Students](#)
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Contacts

Questions can be addressed to:

Subject	Contact	Phone
Recruiting volunteers into research protocols	Human Investigation Committee or Human Subjects Committee	203.785.4688 HRPP@yale.edu ysmhc@yale.edu human.subjects@yale.edu

Roles and Responsibilities

[Human Investigation Committee \(HIC\)](#)

The HIC I, HIC II, HIC III and HIC IV serve as the four Institutional Review Boards or IRBs for biomedical research conducted at Yale University.

[Human Subjects Committee \(HSC\)](#)

The HSC serves as the as the Institutional Review Board for social, behavioral and educational research conducted at Yale University.

References:

DHHS Office for Human Research Protections; IRB Guidebook
http://www.hhs.gov/ohrp/archive/irb/irb_guidebook.htm

Food and Drug Administration (FDA) – Information Sheet Guidance for Institutional Review Boards (IRBs), Clinical Investigators, and Sponsors
<http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm113709.html>

U.S. Department of Education; <http://www.ed.gov/policy/gen/guid/fpcos/ferpa/index.html>

Revision History

Last revised: 11/15/11, 1/18/12, 8/20/12