

Policy II3C Recruitment of Research Participants

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 University of Nevada, Reno (the University) or its research affiliates who conduct recruitment activities for University human subjects research.

Note: Additional regulatory requirements apply to recruitment in Department of Defense-sponsored research; see IRB guidance I1D GD4.

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. Recruitment activities may not commence prior to the recruitment plan being reviewed and approved by an Institutional Review Board (IRB).

Reason for the Policy

Recruitment is considered the start of the participant selection process and is a prelude to the informed consent 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 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

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

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 participants' 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 establishes security and privacy standards for the use and disclosure of "protected health information" (PHI).

Privacy

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

Therapeutic Misconception

The belief that research studies are intended to benefit the participants who enroll in them 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.

I13C1 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.

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.

A variety of methods exist investigators to recruit subjects for research studies. In determining whether or not to approve recruitment methods, the IRB, will consider the populations, settings, and research methods. The most common are described below.

I13C1a Advertisements, Notices and Scripts

Materials 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; internet advertisements and posts; and telephone, 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. However, should an investigator decide at a later date to advertise for participants using a different recruitment method, the advertisement may 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.

Content of Recruitment Materials

Advertisements must contain only the information prospective subjects need to determine their eligibility such as

- the name and address of the investigator or research facility,
- the purpose of the research or the condition under study,
- in summary form, the criteria that will be used to determine eligibility for the study,
- a brief list of benefits to subjects, if any,
- the time or other commitment required of the subjects, and
- the location of the research and the person or office to contact for further information.

For additional IRB considerations and for prohibited content for recruitment materials, see section I13CF.

I13C1b Identification of Potential Participants Through Existing Data (e.g., Clinical and School Records)

Before a researcher may review existing data sets to identify individuals who may be eligible to participate in a research study, IRB review and approval is required in addition to the review and approval from sources holding existing data. Existing data sets may include medical, billing or academic records.

Data sources that are not publicly available may be subject to additional institutional or regulatory requirements prior to access, such as HIPAA requirements for protected health information and FERPA requirements for academic records. 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 or limiting access to only those data elements allowable under FERPA.

If existing data will be reviewed to identified potential subjects, and the persons to whom the information applies are not informed of this review, the investigators must request and justify a waiver of consent.

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. 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.

I13C1c Use of Third Party for Recruitment of Potential Subjects

There may be research that uses a third party to inform potential subjects about 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. Third parties recruiting on behalf of the researchers may *not* collect additional research-related information to determine eligibility. Ideally, third party recruiters provide potential participants with contact information for the researcher and interested individuals may then initiate contact with the researchers. Recruitment methods and materials involving third parties, as with all recruitment methods and materials, require IRB review and approval prior to implementation.

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

I13C1d Development and Use of Recruiting Lists

Investigators may create and maintain lists of research participants who previously took part in research or were screened for but deemed ineligible for other research studies, and who expressed interest in future research participation. In these situations, 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 individual’s data elements to be maintained and ensure the adequacy of 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.

I13C2 Recruitment and Equity in Subject Selection

Recruitment of human research participants from convenience samples is not an acceptable practice. Such recruitment approaches target populations because of their ease of availability rather than for the characteristics that make them an ideal population for the research. These populations may include individuals who are in a compromised position and as such are susceptible to manipulation, influence and coercion, even when the pressures to participate are not real but are imagined or perceived by the persons being recruited.

One method for guarding against inequity in subject selection basis subject select in the following order of preference: adults before children, competent individuals before incompetent individuals and non-institutionalized persons before institutionalized persons.

Researchers are also charged with assessing the existing burden of populations selecting the sample populations an developing recruitment strategies. For example, researchers are cautioned against recruiting individuals burdened with disabilities, poverty, illness and lack of education; or who are institutionalized, unless the research relates directly to the needs of the population.

Equitable recruitment practices require researchers to consider where and how subjects will be recruited and to use a variety of locations and circumstances, to the degree possible. Equity in subject selection considered both the need to not overly sample populations of convenience as well as to ensure that opportunities for eligible individuals are available in multiple settings. The study design should provide for the adequate representation of women and minorities in the study population so that the findings will be meaningful for those groups and they can, therefore, share in the benefits of the research. Adequate representation of women and minorities is particularly important in studies of diseases, disorders and conditions that disproportionately affect them.

Recruiting Non-veterans in VA Research

The IRB allows non-veterans to be entered into VA-approved research studies only when there are insufficient veterans available to complete the study or when the investigator can present a compelling argument to the IRB for the inclusion of non-veterans (e.g., survey of VA employees; study of active duty military; study involving veterans' family members), and the research is relevant to the care of veterans or active duty military personnel.

I13C3 Requirements for Direct Contact with Potential Participants

Investigators 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 participant should questions be raised by him or her about their research rights.

I13C3a 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.

I13C3b 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 her or his work performance evaluation or promotion, or grade is not dependent upon her or his participation.

When practicable, professors recruiting their own students may ask another professor or graduate student unaffiliated with the course to recruit for them; and may design the research so that information about which students did or did not agree to participate are not available to the professor until after grades are posted. If this latter option is exercised, a statement to that effect may be included in the recruitment script.

I13C4 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 obtain more information about the research (i.e., proceed to the consent process). 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.

Additionally, recruitment activities must be carried out settings that afford privacy to the potential participants and that is free of situational or environmental influences or intimidations.

I13C5 Monetary Incentives and Bonuses

Incentives for Investigators or Others to Recruit Subjects

University researchers and staff are prohibited from receiving or dispersing bonuses or incentives for recruitment, referral or enrollment. The IRB may approve recruitment incentives or bonuses for snowball sampling under strict circumstances (see I13C1c above).

Incentives for Subject Participation

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

University policy prohibits paying subjects to participate in research when the research is integrated with a patient's medical care and when it makes no special demands on the patient beyond those of usual medical care.

University policy permits researchers to pay subjects under the following circumstances:

1. the research is not directly intended to enhance the diagnosis or treatment of the medical condition for which the subject is being treated, and the standard of practice in affiliated non-VA institutions is to pay subjects in this situation;
2. the research is a multi-institutional study and subjects at collaborating non-VA institutions are paid for the same participation in the same study at the same rate proposed;
3. in the opinion of the IRB, payment of subjects is appropriate in other comparable situations; or
4. the subject will incur transportation expenses that would not be incurred in the normal course of receiving treatment and are not reimbursed by another mechanism.

II3C6 IRB Review and Approval of Recruitment Procedures

The IRB 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;
4. include the required elements;
5. do not promise free treatment or medication; and
6. do not contain exculpatory language.

II3C7 Special Situations and Exceptions

The use of federally funded clinical trial registries (clinicaltrials.gov) is not considered 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.