



UNIVERSITY OF
SOUTH ALABAMA

IRB SOP 1202
Recruitment of Research Participants

Purpose

The purpose of this Standard Operating Procedure (SOP) is to ensure the IRB is charged with protecting the safety and welfare of human participants through providing a review of the proposed research methodology, including recruitment and advertisement methods. The IRB must prospectively review all aspects of recruitment as planned or envisioned by the Investigator, along with all the information that the participant will see in the process of deciding whether to participate in the research.

Scope

This SOP applies to all human subject's research recruitment activities by USA employees, faculty, and students or by individuals who are members of USA affiliate institutions.

Definitions

Clinician: A physician or service provider who has a treatment relationship with the patient.

Clinical personnel: Persons who are members of the clinician's staff who have a legitimate reason to know identifiable health information by virtue of a treatment relationship with the potential participant.

Finder's fees: Payments to physicians or other professionals for referring individuals to research studies.

Protected Health Information (PHI): includes personal and/or identifiable information about a research participant that may be contained in medical records including but not limited to

name, address, telephone numbers, fax numbers, social security number, medical record number, health insurance number, certificate/license numbers, vehicle and serial numbers, biometric identifiers (voice and fingerprints), full face photographs and any unique identifying numbers or characteristics or codes.

Policy

The IRB will evaluate the selection and recruitment of research participants in accordance with all relevant laws and regulations. The IRB must be particularly cognizant of the special issues or potential problems concerning research involving vulnerable populations. In order to approve research the IRB will determine:

- If the selection of human participants is equitable, taking into account the purpose of the research, the setting in which the research will be conducted and the inclusion/exclusion criteria;
- Whether potential participants are vulnerable to coercion or undue influence; and
- If the recruitment process provides participants with sufficient information and an opportunity to consider whether or not to participate.

1.0 Preparatory to Research

There are several different ways to identify potential research study participants, including recruitment by treating physicians and direct advertising. When conducting research it may be necessary for the PI to review medical records and obtain personal health information (PHI) in order to know if there are enough potential participants who have the condition being studied. If this activity is conducted to identify whether or not potential participants are eligible for the study, it is covered under HIPAA regulations as an activity considered “preparatory to research”. If PHI is needed for recruiting, then the IRB must have approved an appropriate waiver of authorization and waiver of informed consent before PHI may be obtained and used for recruitment. It does not matter if the PI or his/her agent is obtaining information from his/her own patients’ records or not.”

If the person (PI) reviewing the records does not have a clinical relationship with the potential participant, it is necessary for the clinician or his/her personnel to introduce the initial recruitment materials.

2.0 Contacting Prospective Participants Who Were Identified From Medical Records

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

A clinician who is not the PI of a research study may approach his/her patient with information from the PI about the research study. If the potential participant is interested in the research study, the clinician may provide information about the research study and/or provide a contact number to the patient, for more information. Information may be released to the PI if potential participants give permission for their identifying information or contact information to be shared. The clinical personnel may also discuss the patient's Protected Health Information (PHI) with other research personnel, such as the coordinator, as long as the patient first has given his/her verbal permission for this disclosure.

When the PI is not the clinician, the prospective participant's clinician may send a letter informing a potential participant about a study and inviting him/her to participate by contacting the investigator in charge of the study. The letter should not contain any information that may be perceived as undue influence or contain coercive information or language and must be reviewed and approved by the IRB prior to sending it to the prospective participant.

3.0 Follow-up in Mail Questionnaires

An investigator may contact potential participants whose names were obtained outside of the medical record by mail and may enclose a card that the prospective participant can return indicating that he/she is interested in being contacted to participate in a study. Potential participants may be sent two to three letters, but if the person does not respond, the investigator must remove that person from the contact list. All letters to potential participants must be approved by the IRB prior to sending.

4.0 Recruiting Students/Trainees/Employees

An underlying ethical principle in research involving human participants is the belief that a person's participation must be voluntary and based upon full and accurate information. When a student is asked to volunteer in a study being conducted by his/her teacher, the concept of "voluntariness" may be questionable. Students may volunteer to participate under the belief that doing so will place them in a favorable light with the principal investigator/faculty member (e.g., better grade, good recommendation, employment possibilities), or that failure to participate will negatively affect their relationship with the investigator or faculty (e.g., lower grade, less favorable recommendation, being perceived as "uncooperative" and not part of the scientific community). Similar perceptions may apply to an employee/employer relationship. Whenever the potential participant is a student, trainee or employee of the institution, follow *IRB SOP 905: Student and Employees as Research Subjects*.

4.1 External Investigators and Recruitment of Student Population

Investigators from external institutions periodically seek to recruit USA students to participate in a research study on campus. For any USA faculty or administrator receiving an inquiry about participation of USA students, the following steps should proceed to facilitate appropriate review of such requests:

- Obtain IRB approval from the investigator's home institution, accompanied by the proposal and active recruitment method that will be used on USA's campus
- Departmental or administrative official must support the study and active on-campus recruiting
- USA faculty or administrator submits information collected from the external institution to the USA IRB Office
- USA IRB will evaluate the proposal
- USA IRB may consider the external investigator's home institution IRB review sufficient and grant permission, request USA IRB approval or deny on-campus recruitment.

5.0 Recruitment Materials

Direct advertising for study participants begins the informed consent and participant selection process. IRB review and approval is required for all recruitment materials that are intended to solicit participation for a research study. This approval must be given prior to the use of any recruitment materials. For other specific guidance see *IRB SOP 1201 : Advertising for Research Participants*

6.0 Finders' Fees

The USA IRB does not allow the use of finders' fee in research. The USA IRB does not allow the use of Finder's Fees for research studies conducted under its auspices. The concern is that use of Finder's Fees will steer the referral of a patient to a particular protocol rather than to a protocol that may be of most benefit to the participant. The participant, not being aware of the remuneration being paid to the recruiting professional, will not have the full disclosure required for truly informed consent.

Members of the research team are compensated for recruiting subjects as part of their job description and may not receive direct cash payments for individual recruitment.

Ref: Lind SE: Finder's fees for research subjects. *New England Journal of Medicine* 1990; 323: 192-5

Procedures

Before approving a research study the IRB will determine that:

- The selection of participants is equitable, taking into account the purpose of the research, the setting which the research will be conducted and the inclusion/exclusion criteria;
- Potential participants are not vulnerable to coercion or undue influence;
- The inclusion/exclusion criteria are acceptable; and

- The recruitment process provides participants with sufficient opportunity to consider whether to participate.

1.0 Recruitment Methods

- 1.1 Verbal recruitment (via telephone or in-person): investigators must provide the IRB with an oral script of the verbal recruitment process.
- 1.2 Electronic recruitment (via email, web sites, or listservs): investigators must provide the IRB with a version of the email script or web site view detailing the recruitment process and how consent will be obtained. The IRB recommends that researchers follow procedures as outlined in the USA guidance document entitled "Conducting Computer and Internet-Based Research Involving Human Subjects".
- 1.3 Recruitment by mail: Investigators must provide the IRB with materials that would be used for the mailing campaign
- 1.4 Recruitment by advertisements: Investigators must provide the IRB with the intended proposed advertisements, flyers, and ads used in the recruitment process. All newspaper advertisements should adhere to USA's Office of Public Relations template.

2.0 Recruitment Incentives

- 2.1 Investigators often use incentives to enhance research participation to include various methods by offering gift certificates, drawings, vouchers, monetary compensation or class "extra credit". The IRB will consider whether paid participants in research are recruited fairly, informed adequately and paid appropriately.
- 2.2 When using funds obtained from University accounts, investigators must account for monies disbursed during the course of a project. This is a necessary component of financial auditing. However, this accounting must be done in a way that participant confidentiality is not compromised. Using any type of identifier will void confidentiality protection mechanisms and possibly contradict what the participant was informed about in the consent document. Each expense should be tracked by participant ID, the amount paid and when payment occurred and retained in the protocol file.
- 2.3 Investigators must provide the IRB with a full description of how extra-credit incentives will be used. As with monetary incentives, a student may decline to participate in the research, but obtain extra-credit by alternate assignment methods. The student who chooses to participate in the research will be informed of the specific requirements to obtain extra-credit for participating in research, without misleading, coercive, or deceiving information. All students must be ensured they will not be penalized or their grade will not be adversely affected by their decision to not participate in the research.

- 2.4 Compensation may also be provided by entering a drawing. The consent document must include a description of the prize, the odds of winning, the timing of drawing/payment, who will be present during the drawing, and how subjects are to be notified. The term “drawing” rather than “lottery” should be used, as the latter implies purchase of tickets by the participant.

Related Documents

[SOP 1201: Advertising and Subject Recruitment Materials](#)

[SOP 905: Student and Employees as Research Subjects](#)

History:

Effective Date:

Revisions: November, 2018

Responsible Office:

Office of Research Compliance and Assurance