Wayne State University Human Investigation Committee	
Subject:	Recruitment of Research Participants
Section:	
Form Date:	2/2007 (Rev. 03/07/11)
Approvals	1/21/06 Office of the General Counsel, 02/05/07 Steering Committee, 03/19/07 Administrative Approval, 03/07/11 Administrative Approval

Background

Federal regulations require that an Institutional Review Board (IRB) review and have authority to approve, require modifications, or disapprove all research activities involving human participants [45 CFR 46.108(a), 21 CFR 56.108(a), & 38 CFR 16.108(a)]. Further, an IRB is required to ensure that appropriate safeguards exist to protect the rights and welfare of research participants (subjects) 45 CFR 46.111, 21 CFR 56, 38 CFR 16 & VHA Handbook Appendix D]. In fulfilling these responsibilities, an IRB is expected to review all the research documents and activities that influence directly the rights and welfare of potential participants, including methods used to recruit them.

According to the Belmont Report, recruitment of participants for research must be equitable. This means that the Principal Investigator must ensure that, where possible, diversity of ethnicity, socio-economic status, and gender be built into the research design. This helps to assure that a variety of groups have an opportunity to participate in and/or benefit from a research study, and no one group is made to bear the majority of the burdens inherent by participating.

The recruitment process must take into account the privacy and confidentiality rights of potential participants. The requirements set forth in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) for use and disclosure of Protected Health Information (PHI) for research [45 CFR 160 & 164, Subparts A & E] and articulated in the HIC Policy/Procedure "HIPAA Requirements in Research", provide protections against using private and confidential information to contact potential participants for research recruitment without appropriate review and approval by a Privacy Board (at WSU this is the IRB) before the activities are begun.

The IRB must examine all recruitment materials and scripts prior to their use by a research team to determine whether or not the content of such materials are coercive. This is especially important when vulnerable groups are the population of interest for the study. (See HIC Policy/Procedures: "Vulnerable Participants".)

Scope:

This Policy/Procedure applies to all behavioral or biomedical research recruitment activities by WSU employees, faculty, and students or by individuals who are members of WSU 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.

HIC 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. Also, in VAMC research, veterans must be used as participants unless no veterans are available to complete the study [38 CFR 17.45]
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.

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" except at the VA. VA does not consider recruitment to be an "activity 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.

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.

These relationships are addressed in the HIPAA Summary Form. It is important to clearly define the roles of persons doing the initial introduction of the study when completing that form for submission. (See "HIPAA Requirements in Research").

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

Secondary Recruitment

An example of secondary recruitment is when an investigator wishes to obtain the names of family members of a participant for a genetic study. Secondary recruitment should be done by giving a stamped envelope containing the solicitation materials (letter, study brochures, return postcard, etc.) to the participant. In this instance, the participant is asked to address and mail the envelope to his or her relative. If the investigator does not receive a response from the secondary recruit, it is reasonable to ask the study participant to contact the individual to be sure that he or she received the materials. If the person does not respond, the investigator should remove that person from the list of potential participants.

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 then the HIC Policy/Procedure for "Vulnerable Participants: Students, Trainees and Employees" should be followed.

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 HIC Policy/Procedures: "Advertising for Research Participants" and "Compensation for Research Participants".

Finders' Fees

The WSU IRB does not allow the use of finders' fee in research. (See HIC Policy/Procedure: "Finders' Fee").

HIC Procedures:

The Institutional Review Board 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. Also, non-veterans may be entered into VA-approved research studies only when there are insufficient veterans available to complete the study. [38 CFR 17.45]

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.