

IRB Policy 16: Subject Recruitment and Payment

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I. Summary

It is the policy of both the ETSU IRB and the ETSU/VA IRB that non-coercive methods must be used by investigators to recruit subjects. Procedures for enrolling subjects and compensation for subjects must minimize the possibility of coercion or undue influence. The IRB evaluates whether subject selection is fair and equitable by considering both the selection criteria and proposed plans for recruitment of subjects for each research study. Recruitment represents the beginning of the consent process; as such, all recruitment methods and materials must meet ethical guidelines and must be reviewed and approved by the IRB before recruitment begins.

The IRB must ensure that recruitment methods and materials, including payment amount and timing of disbursement to subjects, are not coercive, misleading, or unduly influential. If the circumstances of the research could give rise to any level of undue influence (e.g., payment for subjects' participation, instructors recruiting their own students, supervisors recruiting their direct reports, health care professionals recruiting their own patients), the study team must provide appropriate safeguards and/or assurances that the decision to participate will not affect the relationship.

II. Recruitment of Subjects

Methods for subject recruitment must be addressed in the New Protocol Submission xForm. Potential subjects cannot be specifically identified or contacted until IRB approval is obtained. Researchers may obtain general data relating to the availability of a subject population or obtain documentation support from research sites to ascertain the feasibility of the study prior to IRB review. There are a number of ways to recruit subjects including:

- Advertisements (i.e., flyers, emails, social media or online posts)
- Word of mouth
- Recruitment databases
- Existing professional, clinical or research relationships
- Accessing email lists through other organizations

Healthy Volunteers

When recruiting healthy volunteers, one of the following methods are recommended:

- Use of public advertisement, (i.e., bulletin boards) including telephone number that a potential research subject may call to volunteer for the study.
- Use of a letter briefly explaining the study and including a telephone number that a potential research subject may call to volunteer for the study.
- Any alternative method (i.e., public advertisement, flyers, web site announcements) of contacting volunteers for research.

Patient Recruitment

When a potential research subject is also a patient, i.e., a patient currently receiving treatment or a former patient who is to be recruited for a research study related to a medical problem, the following guidelines are recommended:

- The IRB recognizes that often patients currently under treatment are to be recruited into a research study, and that the physician providing the care and the principal investigator are one and the same. The IRB further recognizes that in these situations a certain degree of unavoidable coercion exists, and the IRB will pay particular attention to the risk/benefit ratio when reviewing such protocols.
- Per HIPAA requirements outlined at 164.508, researchers should obtain written authorization from subjects before using or collecting protected health information (PHI). Authorization must be obtained in writing from prospective subjects. Protected health information includes individually identifiable health information, excluding individually identifiable health information in (i) education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. 1232g; and (ii) records described at 20 U.S.C. 1232g(a)(4)(B)(iv).
- In those protocols where more than minimal risk is involved and the potential benefit to the subject is not direct, the IRB may elect to request that an uninvolved person participate in the patient selection process.
- In those situations where the potential research subject is a patient under the care of a physician other than the investigator, it is recommended that the approval of that physician be obtained before the patient is contacted regarding the study (applicable for studies that involve treatment or other direct patient management decisions).

ETSU Students & Employees

When ETSU students, faculty, or staff are being recruited as potential research subjects, investigators must ensure that appropriate safeguards are in place to avoid undue influence or coercion. The voluntary nature of their participation should be primary, and the recruitment process should emphasize to subjects that neither their academic status nor grades or employment will be affected by

their participation decision. Investigators are discouraged from enrolling students or employees whom they directly supervise and are encouraged to have a co-investigator without a supervisory relationship to the subjects lead those recruitment efforts instead. When recruitment occurs in the classroom, e.g., administering a survey, investigators should consider waiting until the end of the class period to allow students the option of leaving the classroom if they do not wish to participate, and thereby, alleviating pressure to participate. Due care should be given to the type of research conducted in the class or office environment and should allow reasonable alternatives to ensure that subjects' rights and welfare are protected.

III. Research Advertising Materials Guidelines

All subject recruitment materials directed to potential participants including advertisements and/or letters associated with the study must be submitted to the IRB for approval. Materials directed to other audiences (e.g., materials given to health care providers, teachers, or schools who will facilitate recruitment of subjects; news articles not intended for recruitment of subjects) and listings on clinical trial websites which provide basic information limited to title, purpose, study summary, basic eligibility criteria, locations, and contact information do not need to be reviewed by the IRB.

Advertisements to recruit participants should be limited to the information that prospective participants need to determine their eligibility and interest. The following items should be included in advertisements:

- name and address of the Investigator;
- a clear statement that "This is a research study;"
- purpose of the research;
- criteria to be used to determine eligibility in a summary form;
- location of the research (e.g., ETSU);
- a brief description of the study activities, when appropriate; and time or other commitment required
- brief list of potential benefits, if any; and
- name and phone number of the person to contact for further information.

Advertisements may also include a statement that participants will be paid, but should not emphasize the payment amount, by such means as larger or bold type.

Advertisements cannot:

- State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
- Make claims, either explicitly or implicitly, that the drug, biologic, or device is safe or effective for the purposes under investigation.

- Make claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic, or device.
- Use terms such as “new treatment,” “new medication,” or “new drug” without explaining that the test article is investigational.
- Promise free medical treatment when the intent is only to say participants will not be charged for taking part in the investigation.
- Include a coupon or other incentive from the sponsor for a discount on the purchase price of the test article once it has been approved for marketing.
- Include any exculpatory language.

IV. Payment of Participants

When the IRB evaluates the selection of participants, it considers the influence of payments to participants. Payment to research participants is not considered a benefit but a recruitment incentive or way to reimburse subjects for travel or other experiences incurred due to participation. The amount and schedule of all payments should be described in the IRB new protocol submission at the time of initial review, including the amount of payment, and the proposed method and timing of disbursement. The IRB must review this information to assure that the amount, method, or timing of payment are not coercive and do not present undue influence.

Credit for payment should accrue as the study progresses and not be contingent upon the participant completing the entire study. While the entire payment should not be dependent upon completion of the entire study, payment of a small proportion as an incentive for completion is acceptable, providing that such incentive is not coercive. The IRB should determine that the amount paid as a bonus for completion is reasonable and not so large as to unduly induce participants to stay in the study when they would otherwise have withdrawn.

Procedures for prorating payment should the participant withdraw should be considered when submitting the IRB submission and informed consent documents. Unless it creates undue inconvenience or a coercive practice, payment to participants who withdraw from the study may be paid at the time the study would have been completed had they not withdrawn. For example, in a study lasting only a few days, it may be permissible to allow a single payment date at the end of the study, even to participants who withdraw before completion.

For VA Studies: VA policy prohibits paying human 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.

Payment may be permitted, with IRB approval, in the following circumstances:

- ✓ When the study to be performed is not directly intended to enhance the diagnosis or treatment of the medical condition for which the volunteer subject is being treated, and when the standard of practice in affiliated non-VA institutions is to pay subjects in this situation
- ✓ In multi-institutional studies, when human subjects at a collaborating non-VA institution are to be paid for the same participation in the same study at the same rate proposed
- ✓ In other comparable situations in which, in the opinion of the IRB, payment of subjects is appropriate
- ✓ When transportation expenses are incurred by the subject that would not be incurred in the normal course of receiving treatment and which are not reimbursed by any other mechanism.

V. Payment to Investigators

A finder's fee is a payment from the investigator or sponsor to a person who refers a potential participant. Recruitment bonuses are payments from the sponsor to an investigator or organization based on the rate or timing of recruitment. Finder's fees, recruitment bonuses, and other financial incentives paid by a sponsor or investigator or others related to the recruitment of research subjects are prohibited. All payment by sponsors for research conducted by ETSU or VA employees must be made directly to the University, James H. Quillen VAMC, ETSU Research Corporation, or the James H. Quillen VA Research Foundation, as appropriate.

Respondent driven sampling (RDS) process may be allowed when the IRB determines that it is appropriate for the type of research proposed and that the amount of remuneration is non-coercive. If the researcher is requesting payment associated with RDS, the researcher must provide an explanation of the rationale for RDS for that particular study. RDS payments may only be given to participants enrolled in the research study.

For physicians, the Tennessee Board of Medical Examiners deems certain recruitment incentives to be unethical and unprofessional conduct and could be subject to physician disciplinary action. In addition, the Federal anti-Kickback statute prohibits illegal remunerations.

ETSU prohibits all bonus payments for enrollment, including those that would be paid directly to the institution.

VI. Subject Screening

Screening activities start the moment the investigator obtains information about the prospective participant to determine if they are eligible for the research. In

some cases, subject screening to determine eligibility may occur as part of recruitment methods prior to obtaining documentation of informed consent and enrolling the subject in the research. Screening procedures should focus solely on determining eligibility for the research and should involve recording only the minimum necessary information prior to obtaining informed consent. Screening activities to establish eligibility might include:

- Review of medical records, including certain admission or clinic logs that contain identifiable private information
- Review of other private records, such as educational records subject to FERPA
- Asking individuals questions or taking a medical history
- Performing laboratory tests on stored samples, to see if the results are within the required range
- Performing laboratory tests on samples obtained solely for the research, to see if the results are within the required range

The investigator should describe all screening and eligibility procedures in the new protocol submission to ensure that the IRB documents the appropriate determinations for review. If the information or biospecimens used for the purpose of screening, recruiting, or determining the eligibility of subjects include protected health information (PHI), HIPAA applies and HIPAA Authorization may still need to be obtained prior to conducting these screening activities. The IRB's responsibilities related to HIPAA are described in more detail in the IRB Policy 14.

VII. IRB Review

Recruitment methods are described and justified in the IRB new protocol submission, including:

- identification of potential subjects
- plans for contacting potential subjects
- payment arrangements for subjects' participation
- potential undue influence

Recruitment materials directed to potential subjects are attached to the IRB new protocol submission xform, or the modification request xform if new or revised after initial approval.

The IRB will review the information contained in the new protocol submission as well as the advertisement to assure that the material is accurate and is not coercive or unduly optimistic, creating undue influence to the subject to participate. The IRB will review the final copy of all advertisements, including print, audio, or video advertisements. The IRB may request changes to advertisements in order to eliminate or mitigate any potential undue influence or coercion.

The IRB will review the information contained in the new protocol submission regarding any screening or eligibility procedures to ensure appropriate procedures are in place to protect the rights, welfare, privacy and confidentiality of participants.

Per 45 CFR 46.116(g), the IRB may approve screening procedures without the investigator obtaining prior informed consent of the prospective subject or the subject's legally authorized representative only if the solicited information is limited to the minimum necessary for screening/determining eligibility for the main study AND if these procedures are limited to: (a) obtaining information through oral or written communication with the prospective subject or legally authorized representative, or (b) obtaining identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

To qualify, these screening procedures must be brief in duration and limited in nature to focus solely on determining eligibility for the research. Therefore, administration of questionnaires/surveys that increase the potential risk to subjects (e.g. lengthy standardized questionnaires that make a new, or refute an existing, diagnosis; surveys/questionnaires where subjects' responses may place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing; etc.) would require prior informed consent. Creation of new data through means other than oral/written communication with the subject or collection of biospecimens solely for research purposes would also require prior informed consent.

The IRB may request revisions to the screening or eligibility process, as deemed necessary, to ensure that informed consent is appropriately obtained and documented in accordance with regulatory requirements. If the screening, recruiting, or eligibility process includes PHI, HIPAA applies, and the IRB Chair will make and document the required HIPAA determinations in accordance with IRB Policy 14.

VIII. VA Requirements

Non-veterans may be entered into VA approved research studies only when there are insufficient veterans available to complete the study; or when the researcher can present a compelling argument to the IRB for the inclusion (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. All regulations pertaining to the participation of veterans as research subjects pertain to non-veterans subjects enrolled in VA-approved research.

In VA studies, during the recruitment process, researchers must make initial contacts with veterans in person and/or by letter prior to any telephone contact, unless there is written documentation that the participant is willing to be contacted by phone about the study in question or a specific kind of research (e.g. if the prospective participant has diabetes, the participant may indicate a desire to be notified of any diabetes-related research studies). The initial contact must provide a telephone number or other means that veterans can use to verify the study constitutes VA research. (One source of information about clinical trials is <http://www.clinicaltrials.gov>).

For VA studies, researchers must ensure that in later contact, the research team begins telephone calls to the participant by referring to previous contacts and, when applicable, the information provided in the consent document.

In addition, for VA studies, researchers must ensure that the scope of telephone contacts with the participant is limited to topics outlined in IRB-approved protocols and consent documents. In these contacts, researchers must not request social security numbers.

References:

45 CFR 46.116

21 CFR 812.7

38 CFR 17.45, 92

42 U.S.C. '1320a-7b(b)

VHA Directive 1200.05

OHRP Frequently Asked Question (FAQ) "When does compensating subjects undermine informed consent or parental permission?" (2011)

OHRP Guidance "IRB Review of Clinical Trial Websites" (2005)

FDA Guidance "Preparing Notices of Availability of Investigational Medical Devices and for Recruiting Study Subjects" (1999)

FDA Guidance "Recruiting Study Subjects" (1998)

FDA Guidance "Payment and Reimbursement to Research Subjects" (2018)

FDA Guidance "Screening Tests Prior to Study Enrollment" (1998)

Memo, Department of Veterans Affairs, Subject: Researcher Contacts with Veterans, July 10, 2006

Tennessee Board of Medical Examiners Rule 0880-2-.13(4)(t)