

HAPPY NEW YEAR

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ETSU

IRB Review

Announcement

The IRB will be presenting a workshop “How to Submit to the IRB”, March 24, 2008 from 1:30- 2:30pm at the DP Culp Center, Meeting Room 6, 3rd Floor

This workshop will consist of procedures on how and what to submit to the IRB for a study review and approval. If you know of anyone that will benefit from this workshop, let them know. This workshop is for everyone who is interested.



Recruitment, Payment and Advertisements

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. Direct advertising for research participants is considered to be the start of the informed consent and participant selection process.

For VA Studies ONLY: During the recruitment process, researchers must make initial contacts with veterans in person and/or by letter prior to any telephone contact and provide a telephone number or other means that veterans can use to verify the validity of the study (One source of information about clinical trials is <http://www.clinicaltrials.gov>). After recruitment and during the follow-up phase, VA researchers should begin phone calls by referring to previous contacts and the information provided on the informed consent document .In addition, researchers must restrict their telephone and other contacts with veterans to only those procedures and data elements outlined in IRB-approved protocols. In these contacts, researchers must not request social security numbers.

Recruitment of Healthy Volunteers

Methods for subject recruitment must be addressed in the research narrative. When recruiting healthy volunteers, one of the following methods are recommended:

1. Use of public advertisement, (i.e., bulletin boards) including telephone number that a potential research subject may call to volunteer for the study.
2. 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.
3. Any alternative method (i.e., public advertisement, flyers, web site announcements) of contacting volunteers for research.

Recruitment of participants is considered the beginning of the Informed Consent Process.

Note: Items 1-3 above require IRB approval prior to use

Patient Recruitment

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

1. 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.
2. 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: 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).
3. 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.
4. 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).
5. If former research subjects are to be contacted by either the PI or his/her appropriate designee, and asked to participate in follow-up, the individual should be contacted by letter (not telephone). In this instance, prior approval would be required from the IRB (Refer to minor modification requirements).

Research Advertising Materials Guidelines

All advertisements, questionnaires, surveys, testing forms and/or introduction letters associated with the study and intended for subject use or view must be submitted to the IRB for approval.

Advertisements **may not** include the following:

- The ad cannot state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
- The ad cannot make claims, either explicitly or implicitly, that the drug, biologic, or device is safe or effective for the purposes under investigation.
- The ad cannot make claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic, or device.
- The ad cannot use terms such as “new treatment,” “new medication,” or “new drug” without explaining that the test article is investigational.
- The ad cannot promise free medical treatment when the intent is only to say participants will not be charged for taking part in the investigation.
- The ad cannot include any exculpatory language.



Advertisements **may** include the following:

- Advertisements to recruit participants should be limited to the information that prospective participants need to determine their eligibility and interest. When appropriately worded, the following items should be included in advertisements:
 - ◇ name and address of the Investigator;
 - ◇ 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 of the amount to be paid, by such means as larger or bold type.
- The material should clearly state, “This is a Research Study,” or, when appropriate, “This Research Study involves the use of an Investigational Drug or Device.”

IRB Review

The IRB Chair, or his/her designee, may approve advertisements that are easily compared to the approved Informed Consent document through the expedited mechanism. If the reviewer has any doubt or there are any complicating issues involved, the convened board should review the advertising.

The IRB will review the information contained in the advertisement and its method of communication to determine that participants are not coerced.

The IRB will review the final copy of all advertisements, including print advertisements and audio/video tape for broadcast. If an advertisement is to be broadcast, the IRB may review and approve the wording prior to taping. The approval of the final taped message prepared from the IRB-approved text can be given through expedited review.

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. The amount and schedule of all payments should be described in the IRB application 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 application 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.

All information concerning payment, including the amount, method, and schedule of payment(s), should be set forth in the informed consent document and the narrative.

Compensation for participation in a trial offered by a sponsor may not include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

VA Studies have to follow additional rules.

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.

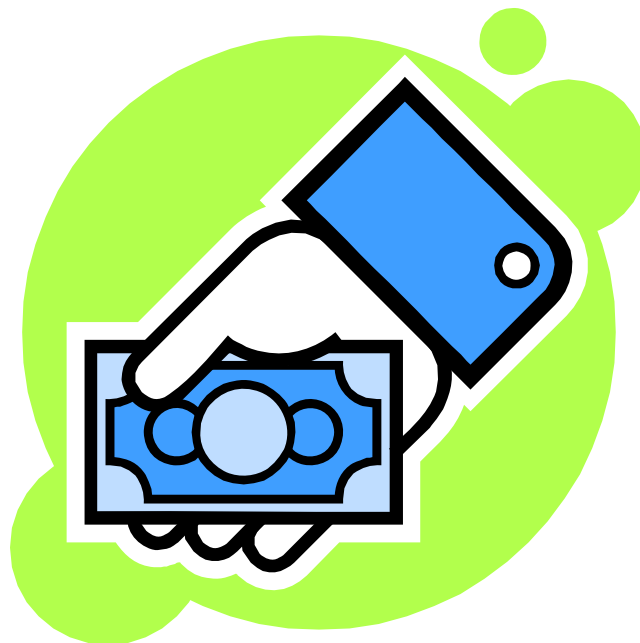
- ⇒ Payment may be permitted, with IRB approval, in the following circumstances:
- ⇒ When the study to be performed is not directly intended to enhance the diagnosis or treatment of the medical condition for which the volunteer subject is being treated, and when the standard of practice in affiliated 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.

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 Foundation, or the James H. Quillen VA Research Foundation, as appropriate.

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



**ETSU
THE OFFICE FOR THE
PROTECTION OF HUMAN
RESEARCH SUBJECTS**

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[We're on the Web]

February 2008

Sun	Mon	Tue	Wed	Thu	Fri	Sat
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3	4	5	6	7	8	9
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17	18	19	20	21	22	23
24	25	26	27	28	29	

- 5-Medical Meeting
- 7- Campus Meeting
- 11- Deadline to submit initial full studies for the March 2008 meeting

March 2008

Sun	Mon	Tue	Wed	Thu	Fri	Sat
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30	31					

- 4-Medical Meeting
- 6- Campus Meeting
- 10- Deadline to submit initial full studies for the April 2008 meeting

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