E. Recruitment and Subject Compensation Issues

1. Recruitment

Recruitment strategies in any form must be reviewed by the IRB PRIOR to their implementation, because they represent the earliest intervention in the informed consent process. There are some recruitment strategies that may or may not be allowed at NU. For instance, the collection of finder’s fees or direct recruitment incentives, and the use of “cold calling” of potential research subjects are not permitted.

a) Finders Fees/Recruitment Incentives:

NU policy prohibits the acceptance or use of finder’s fees, direct recruitment incentives, or bonuses of any type to enroll study subjects. A finder’s fee or recruitment incentive may include bonuses given by sponsors to investigators or research team members (coordinators) to boost enrollment or referral fees given to physicians for referring his/her patients to another investigator’s study. Any payment must be based on project-related effort consistent with the individual’s salary schedule and must be made through the NU payroll system (so as not to exceed 100% effort). Payments to investigators, research team members, or subjects for recruitment that are provided to the individual outside of the NU system are NOT allowed.

b) Cold Calling:

NU policy generally restricts the use of “cold calls” to recruit subjects to research studies. An introductory letter or other informational material must first be sent or given directly to subjects prior to telephone contact. The letter should state that the patient is being contacted “on behalf” of his physician (from NMH, NMFF or RIC). Exceptions may be made on a case-by-case basis, for example, if the potential subjects have previously agreed to be listed on a research registry for future research studies, are currently participating in a study conducted by the same investigator, or are frequently seen by or are well known to the investigator.

Acceptable strategies for recruitment of subjects for research can be varied and may include:

- Advertising to promote the study
- Direct communication with identified groups (patients, students, personnel)
- Referrals from other sources such as other physicians or disease registries

c) Advertising Materials

Recruitment materials, including brochures, flyers, advertisements, posters, audio tapes, video tapes, receptionist scripts and letters to potential subjects, must not contain language or incentives that are designed to create undue influence. The information in recruitment materials should be an accurate presentation of the research study purpose and/or procedures, and should be limited to the presentation of information that prospective subjects need in order to determine their eligibility and interest.

Any material aimed at recruiting potential subjects into a study (including the final copy of the printed advertisement, audio or video tapes or websites) must be reviewed and approved by the IRB prior to being used. Suggested guidelines for an advertisement or recruitment letter or webpage appear below:

- Include the purpose of the project and/or briefly state what is expected of the subject.
- Include the time commitment required of the subject.
- Include the investigator's University department affiliation and where the research will take place.
- List a contact name and phone number.
- Do not include the name of commercial sponsors or products.
• Avoid phrases such as "help needed" or "subjects wanted." The recommended wording is "you are invited" or "participants invited."
• If participants will be paid for their time/effort, it is recommended that the wording "Compensation Available" be used, rather than specifying a specific amount. Compensation should not be excessive to the nature of the project. If the investigator wishes to include a specific amount of compensation in an ad, the Application should include the investigator's justification as to why this is needed. Also, do not emphasize (for example, in large or bold type) the payment or the amount to be paid.
• You may allow compensation for participation in a trial offered by a sponsor to include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.
• Do not state or imply a certainty of a favorable outcome or other benefits beyond what is outlined in the consent document and protocol.
• Do not make claims that the drug, biologic or device is safe or effective for the purposes under investigation.
• Do not make claims that the drug, biologic or device is known to be equal or superior to any other drug, biologic, or device, or make any other claims that are not consistent with FDA labeling
• Do not use terms such as “new treatment,” “new medication,” or “new drug” without explaining that it is investigational.
• Do not promise “free medical treatment,” when the intent is only to say subjects will not be charged for taking part in the investigation.
• Do not include language in the advertising whereby prospective subjects waive or appear to waive any of their legal rights.

Although all forms of communication designed to recruit subjects into a research study should be available to the IRB, NU and the FDA do not consider the following as recruitment materials requiring review by the IRB:

• News stories and press releases that DO NOT contain recruitment information
• Materials given to health care providers intended to solicit research subjects which are not given to or seen by the potential subject (e.g. “dear doctor” letters), do not require IRB approval. However, the process (e.g. contacting health care providers for referrals) is required to have IRB approval.
• Publicity intended for individuals that are not prospective subjects for a particular study
• Listing of clinical trials on a website if limited to title, purpose, protocol summary, eligibility criteria, study sites, and contact information for the investigator.

d) Use of NU staff, students or faculty as research subjects

(1) NU Students as Research Subjects

Consistent with an overall concern that no research subject should be unduly influenced to participate in research, researchers should take particular precautions to avoid the unintentional or subliminal coercion that may occur when a potential research subject is also a student. For this reason, researchers should usually avoid using their own students as research subjects. Researchers who wish to use their own students must provide a good scientific reason, rather than convenience, for selecting those students as research subjects. The research project should be relevant to the topic of the class, and participation should be part of the learning experience for the students.

In instances where investigators can provide a good reason for using their own students in their
research, the IRB generally requires that someone other than the investigator (instructor) obtain informed consent and collect the data. When this is not possible, the IRB will consider other methods for obtaining consent and collecting data that would not reveal to the instructor whether or not a student participated in the research project until after final grades have been determined. The students should be informed of what these procedures are in the Informed Consent Document.

(2) **Extra Credit**

The IRB may approve projects that give extra credit to students who participate in a research project only when alternative means of obtaining equivalent extra credit with equivalent effort is made available to students who do not wish to volunteer as research subjects. The IRB carefully reviews the alternatives to ensure that students are not being coerced into participating. For example, if volunteering for a survey project takes 30 minutes and the student's output is not evaluated for its quality to determine whether extra credit is given, the alternative should involve 30 minutes of effort and the output should not be evaluated (beyond assurance that a good faith effort was made).

The Informed Consent Document should make clear the consequences of withdrawing from a project prior to completion (e.g., will extra credit be given despite withdrawal?). As a general matter, the IRB favors giving credit even if the subject withdraws, unless the student withdraws immediately or there is clear evidence of bad faith on the part of the student.

(3) **Faculty Use of Class Assignments as Research Data**

There may be circumstances when an investigator wishes to use required class assignments (e.g., journal entries in a communications study course) in his or her research. The course syllabus should clearly state that the assignments are required for the course, but that at the end of the semester, the instructor will ask the student to give permission to use the assignments for research purposes. It should be clear that participation will not affect a student's grade. The syllabus, informed consent document, and IRB-approved protocol should describe the procedure to be used to ensure that the instructor does not know who has consented until after final grades have been determined.

(4) **Departmental Subject Pools**

Some departments or colleges employ "subject pools" where students enrolled in introductory courses are recruited by investigators from both within and outside of the department for participation in research projects. Departments or colleges may impose their own standards for the type of research that may be conducted in this setting, and for who may have access to such subjects. Investigators who recruit from "subject pools" are still required to submit their projects to the IRB for review and approval. Beyond the considerations outlined above, academic units may impose their own additional constraints on using students as research subjects. OPRS staff or relevant IRB members are available for consultation in setting up or revising procedures related to departmental subject pools. While not required, departments may consider the departmental subject pool policy and procedures as a “recruitment and subject registry” protocol and may submit it to the IRB for review and approval.

(5) **NU staff or Research Team members as Research Subjects**

The recruitment of NU staff as research subjects should be undertaken with caution. It is important that supervisors in research settings refrain from recruiting or enrolling their own employees and
staff to participate in their research. Because of the power imbalance, and the perception of undue influence, these situations should be avoided. However, the recruitment of NU staff members that are unaffiliated with the research is acceptable.

(6) Referrals from other sources

Referrals from other sources can include the sending of information about ongoing research to other local sources asking that they either pass the information on to potential subjects, or obtain written permission to refer the subject to the study investigator. It can also include distributing study information to appropriate advocacy groups or student groups perhaps by giving lectures or presentations to these groups. As stated previously, this type of recruitment strategy would require review and approval by the IRB prior to implementation but is otherwise not discouraged as long as you follow the strategies as outlined in the “Advertising Materials” section above.

2. Subject Compensation

Payment for participation in research may not be offered to the subject as a means of undue influence, where it might cause someone to assume risks they would not otherwise assume. Rather, it should be a form of recognition for the investment of the subject’s time, loss of wages, or other inconvenience incurred. Payments should be based on the research subject’s time and/or reimbursement for reasonable expenses incurred during his/her participation in the research study. This could include payment for parking, lodging or transportation. For this reason, compensation should not usually be withheld contingent on the subject's completion of the study. In most cases involving continued participation, compensation should be given on a reasonable prorated basis to avoid the impression that the investigator is coercing the subject to continue in a study or is punishing the subject for choosing to withdraw. The complete schedule of the payment plan should be clearly documented within the new study application and the informed consent document reviewed by the subject.

3. Subject Compensation at the Jesse Brown VAMC

The VHA Handbook 1200.5 defines circumstances under which VA subjects may or may not be compensated for participating in a research study. Per VA policy, compensation is not allowed if:

- the proposed research is part of standard of care;
- no unnecessary demands are placed on the subject.

If approved by the NU IRB, VA subjects may be compensated under the following conditions:

- When VA subjects are enrolled in a clinical trial where subjects at non-VA sites are being compensated
- When the IRB determines that compensation of subjects is appropriate
- Reimbursement for transportation is permitted during normal study participation if no other forms of reimbursement are available
- Terms of compensation should be stated clearly in the consent document
- The IRB should ensure that the type of compensation and amount does not foster undue influence or coercion
- Compensation must be reviewed and approved by the IRB and the R and D Committee

VII. New Project study applications and IRB Review and Approval.

Investigators are required to submit an application for IRB review PRIOR to initiating a research project. The online or “eIRB” application tool uses “smart form” technology to guide investigators through the