Research Recruitment Policy

1. INTRODUCTION:
The following recruitment policies should be considered before developing recruitment methods and materials for each protocol. Every recruitment strategy may not be presented here in this policy. Carefully justified alternative approaches will be considered on a case-by-case basis. The Research Administrative Office staff will provide assistance to study teams upon request.

2. OBJECTIVE:
Provide local policy and procedures for recruiting research subjects at the Atlanta VAMC.

3. DEFINITIONS:
“Cold Calling” – The process of contacting potential research subjects (by person-to-person contact, telephone, or letter) when the individual was not expecting such an interaction. “Cold Calling” is not allowed at the Atlanta VAMC.

Research Activities Preparatory to Research – These activities are conducted typically by the PI in the preparation of a protocol. Acceptable activities preparatory to research allow access to PHI to determine for example, if there are sufficient numbers of potential subjects to conduct the research. It is important to note that in activities preparatory to research: 1) only a VA researcher can access the information, 2) only aggregate data may be recorded, 3) no identifiable information can be recorded, 4) information reviewed cannot be used for recruiting subjects, and 5) all requirements for access to data repositories must be followed.

4. RESEARCH RECRUITMENT
Required Approvals Prior to Recruitment
Partial HIPAA Waiver - Before any private health information or identifiable information can be accessed in either medical records, patient registries, clinical databases or data repositories for recruitment purposes (even if the investigator is the treating physician) a partial HIPAA waiver must be approved by the IRB.

Recruitment materials (the text of all research letters*, research flyers, brochures, posters, advertisements, newspaper, television or radio ads, social media, etc.) used as recruitment materials that is intended to be seen or heard by prospective subjects must be reviewed and approved by the IRB (and R&D Committee if submitted with initial protocol approval) and Office of Public Affairs prior to use. Recruitment materials may be submitted as an amendment in eIRB but must not be used until IRB approval has been obtained. *Note: Recruitment letters do not require OPA approval.

Person-to-Person Contact
To avoid “cold-calling” a study team member must receive either a referral or introduction by the patient’s Clinician or Provider prior to initiating person-to-person contact with a potential subject. *Note: A referral or introduction does not have to originate from a Primary Care Provider but must be a clinician who is very familiar with the patient’s health (i.e. mental health provider or...
medical care specialist, etc.). Treating Clinicians/Providers, whose only role in the research is to refer their patients for research participation, must not be members of the research team. Examples of appropriate participant referral by the treating Clinician/Provider include:

1) Clinician/provider gives study information (i.e., approved study flyer, etc.) to his/her patients. The patients will then contact the study team if they are interested in information about the study. The referring clinician is not permitted to conduct study-related activities.

2) Clinician/Provider can make a personal introduction in the clinical setting of the potential subject to a member of the research team.

Recruitment of Subjects From the Investigator’s Own Patients

When the Clinician or Provider is also the Principal Investigator, the Clinician/Investigator must use safeguards to reduce or eliminate coercion. Some examples include:

1) The Clinician/Investigator must provide patients written approved recruitment materials (i.e., flyer, brochure, etc.) about the research first, allowing patients to make further inquiries if they are interested and allowing the patient to contact the study team later if interested in participation. OR

2) A Co-Investigator (who is not the patient’s treating physician) or other study team member must talk to the subject about participating in the research.

It is important to reinforce with all potential subjects during person-to-person contact that participation is voluntary and if they are a veteran, the decision not to participate will not affect their healthcare now or in the future.

Other Person-to-Person Recruitment

It is acceptable to set-up a table in the atrium of the Atlanta VAMC or other approved area within the hospital and personally distribute approved recruitment materials (i.e., flyers, brochures, etc.) to those who voluntarily express an interest in research participation. Note: This process is not “cold calling” because the potential subjects are initiating the contact with the study team. Please contact the Office of Public Affairs to make sure the area is an “approved area” and to schedule the area in advance prior to set-up.

Recruitment Letters

1. To avoid “cold-calling” the study team must have the permission of the Clinician/Provider (must be in writing through email or letter) for his/her patients to be contacted by letter. This permission is obtained after the Clinician/Provider has received copies of the study materials (i.e., study summary, flyer, brochures, etc.) so that he/she has a clear understanding of the research study. Note: If the study team is unable to obtain written approval from the Clinician/Provider, please contact the Clinical Studies Center Manager for assistance and/or alternatives.

2. All recruitment letters must provide equal opportunity (opt-in/opt-out) for the participant to choose to participate. This can be through either the use of the opt-in/opt-out form or included in the text of the letter.
3. All recruitment letters must protect the confidentiality of the identity, diagnosis, prognosis or treatment of any potential research subject relating to drug abuse, alcoholism or alcohol abuse, human immunodeficiency virus or sickle cell anemia or mental health and must never be included in any portion of the letter (including study title, inclusion / exclusion criteria, etc.). Additional information that a potential subject may wish to be kept confidential includes, but is not limited to, a diagnosis or treatment of military sexual trauma, sexually transmitted diseases, or post-traumatic stress syndrome, etc. These terms are sometimes found in the study title, inclusion/exclusion criteria, etc. and must be avoided.

4. All recruitment letters must be on official VA letterhead.

5. All recruitment letters must reference the referring Clinician/Provider by name within the letter or must be co-signed by the Clinician/Provider.

6. All recruitment letters must be either signed or co-signed by the VA Principal Investigator. See Examples of a Referral Letter, Recruitment Letters, and Opt-in/Opt-Out Form

**Telephone Contact as a Follow-up**

1. Research teams must make initial contact in person or by letter prior to making contact by telephone.

2. Contact information of the VA IRB Analyst, Daniel Roysden (404) 712-9749 must be provided during the telephone contact so that potential subjects may verify the study as approved VA research.

See Example of a Follow-up Telephone Script

**Recruitment Flyers/Advertisements**

1. A recruitment flyer must include the following:
   a) Atlanta VAMC and National logos
   b) Title of the research study
   c) Name of the VA PI
   d) Name of VA contact person and their VA telephone number/VA address
   e) IRB number and date the flyer was created in the footer
   f) Indication that this is a research study

2. A recruitment flyer must not include any of the following:
   a) coercive language
   b) a promise of a cure, good outcome, or more benefits than listed in the study documents
   c) a promise of free medical treatment
   d) focus on the financial compensation by bolding or increasing the font
   e) dollar amount of compensation
   f) no claims should be made for FDA test articles that imply safety and effectiveness or equality/superiority to other products on the market
   g) tear-off tabs with telephone numbers or other information

3. Additional information may be added to clarify, such as: a) the purpose of the research study, briefly and in layman’s terms; b) participation is voluntary and willingness to participate will not affect the rights or benefits of the veteran; c) eligibility requirements for participants-don’t use all
but select the most important; d) state the required activities of research participation; e) provide
the time commitment or number of visits required of the subject; f) statement that compensation
for time and/or travel will be provided; g) provision for transportation to and from the AVAMC, if
applicable.
4. The information in the recruitment flyer must be consistent with the Informed Consent and
protocol.
5. A final sample of the recruitment flyer must be included in the IRB submission (showing
actual size of fonts and visual effects). You must use a font that is easy to read and minimizes
clutter on the flyer while making the flyer attractive.
6. After IRB approval (and R&D Committee approval if submitted as part of the initial protocol
submission) the flyer must be reviewed and approved by OPA.
7. After all approvals are obtained, the flyers can be posted in bulletin boards only in designated
areas. (See OPA and CSC for appropriate areas for posting.)
8. Only flyers for VA approved research can be posted at the Atlanta VA.

Note: In general, CSP and/or CIRB studies are not able to create/edit recruitment flyers to
include local requirements. These recruitment flyers also require approval from OPA prior to
posting.
See Example of a Recruitment Flyer

Social Media
Only the Atlanta VAMC facility Facebook page and Twitter account may be used to advertise
VA research studies and recruit potential participants. Study teams must contact the Office of
Public Affairs (OPA) for guidance on posting ads to the facility's Facebook or Twitter account.
Public Internet sites such as “Craig’s List” must not be used to recruit or advertise for VA
research. MyHealththeVet is not to be used for subject recruitment.

Recruitment of Employees or Students
Employees or students who are directly supervised by the investigator must not participate in
the investigator’s interventional research (i.e., studies that include procedures, treatments,
medication, etc.). Employees or students who are veterans that would like to participate in
research (when the investigator is also their supervisor) should contact the Research Office for
appropriate guidance prior to enrollment.

VA Central IRB (CIRB) and Cooperative Study (CSP) Recruitment
In general, coordinators for CIRB and/or CSP studies are not able to create/edit recruitment
materials to include local requirements. Please check with the CIRB and/or CSP coordinating
center to determine if the recruitment materials may be edited for local requirements prior to
use.