

Date Prepared:	Title: Research Recruitment Policy	Revision #1.0
Effective Date: 01/31/2023	Prepared By: Clinical Studies Center	CSCSOP-4
Reviewed By:	Human Research Protections Program	Date Reviewed: 11/10/2022
Approved By:	Clinical Studies Center	Date Approved: 01/31/2023

Purpose:

The Office of Research Development (ORD) provides guidance on research conduct related to recruiting for VA approved research projects to protect the privacy of potential research participants and the protection of human subjects in VA research. This Recruitment Policy is to document and describe the rules and best practices to follow while recruiting participants for research projects.

Scope:

This policy applies to all Investigators and Research Service Line staff recruiting for research projects approved by the Atlanta VA R&D Committee.

Definitions:

Cold Calling: Making contact by telephone when the potential subject is not expecting contact.
Letter: Written communication in hardcopy or electronic form

Policy:**1) Recruiting Requirements**

- a) During the recruitment process, making initial contact with potential subjects should be done in person or by letter prior to initiating any telephone contact, unless there is written documentation that the subject is willing to be contacted by telephone about the study in question or a specific kind of research as outlined in the study. **Cold calling is strictly prohibited.**¹
- b) It is important to reinforce with all potential subjects during recruitment that participation is voluntary, refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- c) The contact information for the Research Compliance Officer (404-321-6111 x206964) must be provided in all initial communications, written or verbal, so potential subjects can verify the study as approved VA research
- d) When the Clinician or Provider is also the Principal Investigator, the Clinician/Investigator must use safeguards to reduce or eliminate coercion.
- e) 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, a partial or complete HIPAA waiver must be approved by the IRB. This applies even if the investigator is the treating physician.

- f) Employees or students who are directly supervised by the investigator must not enroll in the investigator's interventional research (i.e., studies that include procedures, treatments, medication, etc.).
- g) VA clinicians, in the normal course of their clinical duties, are permitted to discuss specific research studies with their patients where appropriate and may refer them to a non-VA investigator for more information about a non-VA study.⁵ Please see the Referring Veterans to Non-VA studies SOP on the AVAHCS Human Studies website.
- h) Recruitment methods and recruitment materials, including recruitment emails, that are intended to be seen or heard by prospective subjects must be reviewed and approved prior to use by the:
 - i) IRB of record either at time of initial submission or via an amendment
 - ii) AVAHCS R&D Committee (if submitted with the study for initial approval)

2) Permitted Recruitment Methods

- a) In Person Recruitment
 - i) Approval from the specialty department must be granted before starting targeted clinic-based recruiting
 - ii) Offsite recruiting is allowed when approved by the IRB as part of the recruitment plan
 - iii) Tables can be set up in the AVAHCS medical center atrium with approval from Education Department, in the cafeteria with approval from cafeteria manager or in the various clinics throughout the AVAHCS medical center to distribute approved recruitment materials to those who voluntarily express an interest in research participation.
- b) Recruitment Letters
 - i) Letters can be sent via USPS, UPS, FedEx, or email
 - ii) All recruitment letters must provide equal opportunity (opt-in/opt-out) for the participant to choose to participate. This can be through the use of the opt-in/opt-out form or included in the text of the letter. (See Supplement A for example letters and Opt-In/Out-Out Form)
 - iii) All recruitment letters must protect the confidentiality of the identity, diagnosis, prognosis, or treatment of any potential research subject relating to, but not limited 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.
 - iv) All hardcopy recruitment letters must be on official VA letterhead.
 - v) All recruitment letters must be either signed or co-signed by the VA Principal Investigator.
 - vi) All recruitment letters must reference the referring Clinician/Provider by name within the letter or must be co-signed by the Clinician/Provider.
 - vii) 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. 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.

- viii) Email
 - (1) Emailed recruitment communications must be sent from a VA Outlook account with encryption
 - (2) Emailing recruitment material as a recruitment strategy must be approved by IRB and/or R&D Committees as applicable per section 1.h) of this document
 - (3) Attachments such as recruitment letters and materials being sent to potential subjects must be approved by the IRB and/or R&D Committee as applicable per section 1.h) of this document
 - (4) Text of emails and standardized communications must be approved by the IRB and/or R&D Committee as applicable per section 1.h) of this document
 - (5) Verification of correct email address is required to avoid sending emails to unintended recipients
 - (6) Avoid using sensitive information in case the email is received by an unintended recipient
 - (7) The subject line may not include any PHI/PII or other sensitive information since it cannot be encrypted⁶
 - (8) Recruitment emails must not include links to websites that are publicly accessible and would allow the reader to conclude that the individual has a specific diagnosis or condition⁶
- c) Recruitment Flyers, Posters, and Brochures
 - i) Recruitment material should be created in collaboration with Atlanta VA Medical Media dept., unless the sponsor provides a template
 - ii) A recruitment flyer must include the following:
 - (1) Atlanta VAHCS and National logos
 - (2) Title of the research study
 - (3) Name of the VA PI
 - (4) Name of VA contact person and their VA telephone number
 - (5) IRB number
 - (6) Version date of the flyer in the footer
 - (7) Indication that this is a research study
 - iii) A recruitment flyer must not include any of the following:
 - (1) Coercive language
 - (2) Promise of a cure, good outcome, or more benefits than listed in the study documents
 - (3) Promise of free medical treatment
 - (4) Focus on the financial compensation by bolding or increasing the font
 - (5) Dollar amount of compensation
 - (6) No claims should be made for FDA test articles that imply safety and effectiveness or equality/superiority to other products on the market
 - (7) Tear-off tabs with telephone numbers or other information
 - iv) The information in the recruitment flyer must be consistent with the Informed Consent and protocol. After all approvals are obtained, the team should send the flyers to the Clinical Study Center so the flyers can be posted in bulletin boards only in designated areas. (See CSC or OPA for appropriate areas for posting)
- d) Telephone
 - i) Initial contact can be made my phone if the potential participant has provided written approval to be contacted by phone (ex. through a registry)
 - ii) Proactive-Calling for Subject Recruitment per ORD's definition is allowed when approved by ORD and the IRB^{2,3}

- (1) Atlanta Research Office will submit requests for Proactive-Calling to ORD on behalf of the research team
- e) Recruitment via text messages is not currently approved for local use
- f) Social media, VA TV, radio, and newspaper
 - i) Material for social media, VA TV, and newspaper must be created in collaboration with Atlanta VA Medical Media department
 - ii) The AVAHCS Office of Public Affairs (OPA) is to be contacted to post recruitment material on VA TV, Facebook, Twitter, newspaper or radio advertisements
- g) MyHealthVet
 - i) Recruitment via MyHealthVet is not currently approved⁴

3) Prohibited Recruitment Methods

- a) Craigslist
- b) Emory Research Match
- c) AllyResearch.org

Supplements

- 1) Supplement A: Recruitment Templates

References:

- 1) VHA Directive 1200.05(2), Requirements for the Protection of Human Subjects in Research, https://www.va.gov/vhapublications/ViewPublication.asp?pub_ID=8171
- 2) ORD – Proactive Calling for Subject Recruitment, [Proactive Calling for Subject Recruitment - Home \(sharepoint.com\)](#)
- 3) ORD Webinar “Recruitment by Phone” August 24, 2021, <https://www.research.va.gov/programs/orppe/education/webinars/orppe-082421.cfm>
- 4) ORD – “Guidance for VA Researchers on the Use of My HealtheVet Secure Messaging”, <https://www.research.va.gov/resources/policies/guidance/MyHealtheVet-SecureMessaging.pdf>
- 5) Referring to Non-VA Studies Policy, <https://www.va.gov/atlanta-health-care/research/human-studies/>
- 6) ORD - Draft Guidance on the Use of Electronic Mail and Electronic Text Messaging for Recruiting and Communicating with VA Subjects in VA Research, July 28, 2017, • [Electronic Mail and Texting: Draft Guidance on the Use of Electronic Mail and Electronic Text Messaging for Recruiting and Communicating with VA Subjects in VA Research \(July 28, 2017\)](#)

Revision History:

Revision	Date	Description of major changes	Requested By
1.0	1.31.2023	<ul style="list-style-type: none"> • Modified to new template • Requirement for all electronic recruitment material to be sent encrypted for a VA account 	CSC