

Version Number: 2	Research & Development Policy 151-19	Supersedes Document Dated: 3/2012
Effective Date: 2/10/2014	Human Research Participant Outreach Program	Expiration Date: 2/10/2018

1. PURPOSE:

To explain procedures for the Research Participant Outreach Program and delegate responsibilities for the conduct of outreach activities to human research subjects and their communities.

2. POLICY:

Per VHA Directive 2008-079, and out of “respect for persons” (a principle of the Belmont Report), this SOP ensures that established mechanisms for research outreach are reliable and that human research subjects are made aware of the venues that allow them the opportunity to enhance their understanding of and involvement in the research process.

3. PROCEDURES:

The procedures fulfilling the policy for the Research Outreach Program at the Syracuse VAMC include the following:

- a. The Outreach Program applies to all potential, present and former human research subjects.
- b. Any prospective research participant (or their surrogate) who is approached to take part in a study shall be provided with the informational brochure, “Volunteering in Research - Here are some things you need to know.”
- c. If a Veteran who is a potential subject enrolls in a research study, the study team is responsible for documenting in the subject’s CPRS Research Study Initiation Note that the brochure was provided.
- d. Informational brochures will be made available to Veterans on a general basis in areas where they may potentially be recruited, such as clinic waiting rooms.
- e. Every research informed consent document will include contact information for the investigator and study staff, as well as a person independent of the research team, such as the IRB Chair or the Veteran Advocate, whom subjects may contact when the research team is unavailable or in cases where the subject does not wish to speak to study team members. The study team will reinforce the subject’s option to contact these individuals to discuss questions or concerns, to offer input, or to obtain information.
- f. The IRB Office will conduct additional outreach through participation in the local Research Week activities available to the Medical Center as well as

provide the informational brochure to new veterans at the bi-weekly Veteran Benefit Seminars. These outreach activities will be conducted in order to enhance the understanding of subjects, prospective subjects and our VA Medical Center community.

4. RESPONSIBILITIES:

- a. The Facility Director is responsible for the establishment and implementation of the Research Participant Outreach Program as detailed in this policy. This includes venues for research subjects and their designated representatives to obtain information, discuss their questions and concerns, and offer their input.
- b. The Associate Chief of Staff for Research (ACOS/R) is responsible for assuring that local investigators are provided and maintain adequate supplies of the informational brochure "Volunteering in Research - Here are some things that you need to know."
- c. The Research Compliance Officer (RCO) will confirm that elements of the research participant outreach program were properly documented. This includes confirming that the PI/study team documented in the Research Study Initiation Note that the VA informational brochure was handed out, and that the contact persons section of the consent is present and accurate.
- d. The Investigator is responsible for providing research subjects with the informational brochure "Volunteering in Research - Here are some things you need to know," even if written documentation of informed consent is waived. Furthermore, the Investigator must ensure that the CPRS Research Study Initiation Note documents that a copy of this brochure was given to the subject. This requirement is waived when either all CPRS study documentation has been waived by the IRB or when informed consent has been waived by the IRB.
- e. The IRB is responsible for ensuring that the contact information in all approved informed consent documents is accurate, appropriate and in compliance with federal and VHA regulations.

5. REFERENCES:

VHA Directive 2008-079
VHA Handbook 1200.05
The Belmont Report



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