

SOP# HRP 01.16

Version:	2.1	Origin:	2.0
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Changes:	Revisions for AAHRP Step 1 review (5/7/11)	New Version #:	2.1
Approved:	Christopher T. Bever, ACOS/R&D Date		
File Name:	Participant Outreach (HRP 01.16)201v.2.1		

### RESEARCH PARTICIPANT OUTREACH PROGRAM (RPOP)

**OBJECTIVE:**

- To establish a documented process for outreach to former, current and future research participants;
- To establish a documented process to inform prospective research participants about research and their rights as research participants.
- To establish a documented process for research participants to express their questions and concerns.
- To evaluate the effectiveness of outreach activities to former, current, and future research participants.

**SCOPE & POLICY:**

On November 17, 2008 the VHA issued Directive 2000-079, "Research Participant Outreach Program" (RPOP). The Directive set out a policy establishing Research Participant Outreach Programs at VHA facilities performing human research.

The VAMHCS Research & Development (R&D) Service concurs with the VHA's stated view that participants' questions and concerns help identify ways to enhance safeguards, thereby better protect participants' rights and welfare. Research Participant Outreach Programs not only help improve relationships with, and safety of, research participants, they can help improve public trust in VA research programs.

Prior to this VHA Directive, the VAMHCS R&D Service had periodically displayed a poster with informational brochures in a public area of the VAMHCS, conducted outreach on VA Research Days, conducted and reported on a research participant satisfaction survey project, included the VAMHCS Research Compliance Office contact information on VAMHCS informed consent forms, and, through the R&D Service internet site, publicized the Research Compliance Office as a contact for complaints and suggestions. A participant outreach program has been included in the VAMHCS Human Research Protection Program since 2003.

It is the policy of the VAMHCS R&D Service to seek feedback from current, prospective or past research participants or their designated representatives by establishing and promoting a Research Participant Outreach Program (RPOP).

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## RESPONSIBILITIES:

The Medical Center Director is responsible for ensuring the local Research Participant Outreach Program is established to include:

- A reliable mechanism for research participants to communicate with research project investigators, and with an informed VA representative who is independent of the research project in question (e.g., providing contact information in the informed consent form);
- Making available the informational brochure, "Volunteering in Research – Here are some things you need to know," to potential research participants in settings where participants may be recruited (e.g., clinic waiting areas), and to each prospective participant when that individual is approached to take part in a project;
- Venues for participants and their designated representatives to obtain information, discuss their questions and concerns, and offer their input;
- Educational activities for research participants and their communities

The VAMHCS ACOS/R&D and the VAMHCS Human and Animal Research Protections Officer (HARPO) are responsible for the implementation of this policy.

The Director of Research Human and Animal Research Protections Officer (HARPO)) is responsible for:

- Scheduling poster displays, electronic messages and other potential avenues of community outreach through the VAMHCS Office of Public & Community Relations.
- Conducting public education and survey activities at VA Research Day and/or other opportunities for public outreach;
- Maintenance of the Research Service website, ensuring that contact information is accurate;
- Intake of the comments, complaints and suggestions;
- Conducting or supervising the follow-up on the comments, complaints and suggestions;
- Conducting satisfaction surveys to assess the experiences of VAMHCS research participants.

The Research Compliance Officer (RCO) is responsible for overseeing and evaluating the VAMHCS Research Participant Outreach Program through quarterly audits of clinics and waiting areas & investigator brochure supply to see if the brochures are readily available to potential research participants and HARPO outreach activities.

The Research & Development Committee (RDC) is responsible for evaluating audits assessing the effectiveness of the VAMHCS Research Participant Outreach Program.

The Principal Investigator is responsible for:

- Ensuring that research participants can express concerns, complaints or suggestions without fear of threat, restraint, discrimination or reprisal;
- Distributing the VHA brochure, "Volunteering in Research – Here are some things you need to know" to potential research participants in settings where they may recruit participants (e.g., clinic waiting areas), and to each prospective participant, and surrogate where necessary, when an individual is approached to take part in a project;
- Obtaining the "Volunteering in research..." brochure from the HARPO in order to ensure that the brochure identifies a contact for participants seeking information from an individual independent of the research study.
- Educating potential participants that the IRB, and the HARPO are independent of the research and are available for expressing questions or concerns;
- Informing study participants and their families/advocates during the informed consent process that complaints can be lodged with the HARPO, and the IRB;
- Ensuring that the HARPO has accurate information if/when a comment/complaint has been lodged.

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## SEE ALSO

VAMHCS Research Service SOP  
VAMHCS Research Service SOP

HRP 01.02: Human Research Protection Program  
HRP 01.07: Comments, Complaints and Suggestions  
Related to the Human Research Protection Program

## PROCEDURES:

1. The VAMHCS Human and Animal Research Protections Officer (HARPO) conducts participant outreach activities:
  - 1.1. Responds to and processes participants' or others' complaints, comments and suggestions. This is done according to HRP 01.07 (Comments, Complaints and Suggestions Related to the Human Research Protection Program)
    - 1.1.1. The HARPO accesses CICERO for information regarding the study when necessary
    - 1.1.2. The HARPO contacts the investigator to obtain and verify current information about the study when participant questions arise.
  - 1.2. Ensures that the VHA brochures, "Volunteering in Research – Here are some things you need to know" are distributed to investigators and potential participants.
    - 1.2.1. Brochures need to be labeled with contact information for the HARPO.
    - 1.2.2. The HARPO periodically displays the COACH informational poster in public areas throughout the VAMHCS.
  - 1.3. Maintains current information on the R&D Service website ([www.maryland.research.va.gov](http://www.maryland.research.va.gov)), in particular:
    - 1.3.1. the "Contact Us" page (contains instructions to the community for expressing complaints, comments and suggestions) and
    - 1.3.2. the "For Investigators" page (instructions to investigators and an active link to the COACH website for information on ordering brochures).
  - 1.4. Performs educational outreach activities at the annual VA Research Day.
  - 1.5. Ensures that the IRB's ICF templates contain the contact information for a VAMHCS individual who is independent of the study (HARPO, RCO, etc.)
  - 1.6. Contacts research participants to assess their satisfaction with their research experience.
    - 1.6.1. VAMHCS informed consent forms ask permission to contact participants for this purpose
    - 1.6.2. Schedules educational activities or other outreach in the community
  - 1.7. Establishes an annual plan for evaluation and improvement of the RPOP.
    - 1.7.1. The plan contains at least one goal and at least one measure of the goal.
    - 1.7.2. The plan is presented to the RDC with progress reports as requested by the RDC.
2. Investigators educate current and potential participants in the following ways:
  - 2.1. Distribute the VHA brochure, "Volunteering in Research – Here are some things you need to know" during their recruitment and enrollment activities to potential research participants in settings where they may recruit participants (e.g., clinic waiting areas), and to each prospective participant, and surrogate where necessary, when an individual is approached to take part in a project.
    - 2.1.1. This requirement applies when written documentation of informed consent is waived, but not when informed consent has been waived. NOTE: The Institutional Review Board (IRB) may waive informed consent altogether or it may waive written documentation of the informed consent but still require that informed consent be obtained from the subject or surrogate
    - 2.1.2. Investigators obtain the brochures through the HARPO because those brochures are labeled with contact information for the HARPO. Larger Centers should make

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arrangements with the HARPO to order brochures directly from COACH and to properly label the brochures with HARPO contact information.

2.1.3. Establish written procedures to make the brochures available to current and potential participants through their clinics and other recruitment activities.

2.1.4. Establish written procedures to document outreach activities (for example, how many brochures distributed, reasons why individuals decline the brochure, etc.). This will be assessed at the time of the triennial audits.

2.2. At the time of enrollment and during the consent process, investigators or delegated research staff inform the participant that the HARPO, IRB and the RCO are independent of the research and are available for expressing questions or concerns.

~~2.2.1, 2.2.1.~~ VAMHCS informed consent forms contain contact information for the investigator and study staff, as well the and the UMB IRB as persons independent of the research team for when the research staff cannot be reached, or if the participants wish to talk to someone other than the research staff, and/or the participants wish to voice concerns or complaints about the research.

2.3. Investigators are encouraged to conduct activities to:

- Receive general or protocol-specific feedback from the veteran community, and to
- Involve members of the community in the research process, including the design and implementation of research and the dissemination of results (when appropriate).

Possible mechanisms are:

- Establishment of focus groups,
- Establishment of veteran community advisory boards,
- Newsletters or other forms of information,
- Other mechanisms practical to the investigator's target groups.

REFERENCES:

VHA Directive 2008-079	Research Participants Outreach Program
VHA Handbook 1200.05, 5 (10/15/10)	Requirements for the Protection of Human Subjects in Research