

SOP# HRP 01.16/PM #032

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RESEARCH PARTICIPANT OUTREACH PROGRAM (RPOP)

OBJECTIVE:

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

BACKGROUND:

[On November 12, 2014 VHA Office of Research & Development issued revised VHA Handbook 1200.05. This handbook and the expiration of VHA Directive 2000-079 remove the requirements for a "Research Participant Outreach Program" \(RPOP\).](#)

However, the VAMHCS Research & Development (R&D) Service encourages VAMHCS investigators and research staff to integrate RPOP actions into their research programs and interactions with the community. Participants' questions and concerns can identify ways to enhance safeguards and can improve relationships with research participants, thereby improving public trust in VA research programs.

It is a goal of the VAMHCS R&D Service to seek feedback from current, prospective or past research participants or their designated representatives by promoting a RPOP.

RESPONSIBILITIES:

The Human and Animal Research Protections Officer (HARPO) is instrumental in promoting activities that enhance the public's and the VAMHCS research community's understanding of the conduct of human research. Possible activities may include:

- Making available the informational brochure, "Volunteering in Research – Here are some things you need to know," to investigators and to VAMHCS areas;
- Educational activities for research participants and their communities
- 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;

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- 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 Principal Investigator:

- Is responsible for providing 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);
- Is responsible for ensuring that research participants can express concerns, complaints or suggestions without fear of threat, restraint, discrimination or reprisal;
- Is encouraged to distribute 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;
- Is responsible for educating potential participants that the IRB, and the HARPO are independent of the research and are available for expressing questions or concerns;
- Is responsible for informing study participants and their families/advocates during the informed consent process that complaints can be lodged with the HARPO, and the IRB;
- Is responsible for ensuring that the HARPO has accurate information if/when a comment/complaint has been lodged.

SEE ALSO

VAMHCS Research Service HRPP	HRP 01.02: Human Research Protection Program
VAMHCS Research Service Process Module	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)
 - 1.2. Ensures that the VHA brochures, “Volunteering in Research – Here are some things you need to know” are made available to investigators and potential participants and periodically displays the COACH informational poster in public areas in the VAMHCS.
 - 1.3. Maintains current information on the R&D Service website (www.maryland.research.va.gov).
 - 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. May contact 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
2. Investigators educate current and potential participants in the following ways:
 - 2.1. Are encouraged to distribute the VHA brochure, “Volunteering in Research – Here are some things you need to know” during recruitment and enrollment activities and in settings where they may recruit participants (e.g., clinic waiting areas).

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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.

2.3. 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.