

November 17, 2008

RESEARCH PARTICIPANT OUTREACH PROGRAM

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policy establishing the Research Participant Outreach Programs at VHA facilities performing human research.

2. BACKGROUND: The Department of Veterans Affairs (VA) is guided by the ethical principles set forth in the Belmont Report “Ethical Principles and Guidelines for the Protection of Human Subjects of Research” published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Belmont Report addresses some of the ethical questions about research involving human subjects. It provides three comprehensive principles to provide an analytical framework to guide the resolution of ethical problems arising from research involving human subjects. The principles are “Respect for Persons,” “Beneficence,” and “Justice.” Respect for persons incorporates the conviction that individuals are to be treated as autonomous agents. Informing research participants about and involving them in the research process can help them make better-informed decisions as to whether or not to participate in a given research project. In addition, their questions and concerns help identify ways to enhance safeguards, thereby better protecting their 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.

3. POLICY: It is VHA policy that each VHA facility conducting human research establish a Research Participant Outreach Program for current, prospective, or past research participants or their designated representatives.

4. ACTION

a. **Facility Director.** The facility Director is responsible for ensuring the local Research Participant Outreach Program is established and implemented no later than February 28, 2009, to include:

(1) 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);

(2) 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;

(3) Venues for participants and their designated representatives to obtain information, discuss their questions and concerns, and offer their input;

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(4) Educational activities for research participants and their communities.

b. **Associate Chief of Staff (ACOS) for Research and Development (R&D)**. The ACOS for R&D is responsible for:

(1) Implementing the local Research Participant Outreach Program.

(2) Ensuring local investigators have an adequate supply of the brochure, “Volunteering in Research – Here are some things you need to know.” **NOTE:** *Copies of the brochure can be ordered in bulk from the VA Office of Research and Development’s Center On Advice and Compliance Help (COACH) at <http://www.research.va.gov/programs/pride/resources/order.cfm>.*

c. **Research Compliance Officer (RCO)**. The RCO is responsible for overseeing and evaluating the facility Research Participant Outreach Program.

d. **Investigator**. The investigator is responsible for making available the informational 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. 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 just waive written documentation of the informed consent but still require that informed consent be obtained from the subject or surrogate.* In addition, the investigator is responsible for ensuring that all consent forms must provide participants with contact information for the investigator and study staff, as well as a person 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. The investigator is also responsible for informing the independent contact person regarding the relevant details of the study, and for documenting that this contact person has been informed, to ensure their ability to render proper assistance to potential subjects.

5. REFERENCE

a. Belmont Report “Ethical Principles and Guidelines for the Protection of Human Subjects of Research.”

b. VHA Handbook 1200.05.

6. RESPONSIBILITY: The Office of Research and Development (12) is responsible for the content of this Directive. Questions may be referred to the Office of Research and Development’s Program for Research Integrity Development and Education at (877) 254-3130.

7. RECISSIONS: None. This VHA Directive expires November 30, 2013.

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FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 11/18/08