



**Department of Veterans Affairs
Jesse Brown VA Medical Center
820 S. Damen Avenue
Chicago, IL. 60612**

R&D 537/151
July 13, 2011
Version 1.3

SOP: RESEARCH PATIENT OUTREACH PROGRAM

PURPOSE

To educate patients and their communities about the Jesse Brown VA Research Service activities including understanding what research entails, ethical guidelines of conducting research, and potential benefits and risks to volunteer research subjects. Additionally, we want to conduct proactive outreach activities to highlight the connection between research achievements and improvements in veterans health and health care service delivery to current, prospective, or past research subjects.

POLICY

To comply with the ethical principal of respect for persons participating in research and maximize their involvement in the research process, including proactive outreach activities for current, prospective, or past research subjects or their designated representatives.

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 subjects 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 Subject Outreach Programs not only help improve relationships with, and safety of, research subjects, they can help improve public trust in VA research programs.

RESPONSIBILITIES

1. The Medical Center Director is responsible for oversight of all aspects of the human research program at Jesse Brown VA Medical Center including the research subject outreach program.
2. The Associate Chief of Staff for Research and Development (ACOS/R&D) is responsible for:
 - a) implementing the local Research Subject Outreach Program.
 - b) Designating a Patient Outreach Coordinator to conduct outreach activities to JBVAMC patients as well as affiliate CBOC locations.
 - c) Designate Research Administration Staff to conduct outreach activities during VA National Research Week.
 - d) Ensuring JBVAMC human subject research investigators have an adequate supply of VA Research brochures, including “Volunteering in Research and “Safeguarding Veterans Personal Information.”
3. The Research Compliance Officer (RCO) is responsible for overseeing & evaluating the JBVAMC Research Subjects Outreach Program.
4. The Investigator is responsible for making available the informational brochure, “Volunteering in Research” and “Safeguarding Veterans Personal Information” in clinic or waiting areas to each prospective subject, and surrogate where necessary. In addition, the investigator is responsible for ensuring that all consent forms must provide subjects with contact information for the investigator and the study staff, as well as a person independent of a research team for when the research staff cannot be reached, or if subjects wish to talk to someone other than the research staff, and or the subjects wish to voice concerns or complaints about the research.

PROCEDURES

1. The ACOS and Patient Outreach Coordinator work on strategic outreach activities to investigators at our affiliate institutions to promote partnerships that will increase overall research activity at Jesse Brown VAMC and its Community-Based Outpatient Clinics benefitting the patient and the researchers.
2. The Patient Outreach Coordinator holds informal meetings with prospective research subjects frequently to give them better understanding about Jesse Brown VA research. These are done at JBVAMC as well as the affiliate Community-Based Outpatient Clinics.
3. The JBVAMC promotes the involvement of community members, when

appropriate, in the design and implementation of research and the dissemination of results.

4. The Jesse Brown VA Medical Center celebrates **VA Research Week** each year during the 1st week of May. The Patient Outreach Coordinator in the R&D office coordinates with the ACOS, AO, and Research Administration staff to coordinate VA National Research Week activities. The Patient Outreach Coordinator invites all VA researchers to present their research to both clinicians and veterans alike to highlight our VA research projects and accomplishments as a part of outreach activities for current, prospective, or past research subjects or their designated representatives or their community. The investigators and their staff are also available to respond to any research related questions for clinical staff presentations.
5. The Patient Outreach Coordinator is responsible for ensuring that JBVAMC investigators have an adequate supply of the brochure, “Volunteering in Research” and “Safeguarding Veterans Personal Information”. It is also the responsibility of the Patient Outreach Coordinator to ensure that “Volunteering in Research” and “Safeguarding Veterans Personal Information” brochures are distributed in various clinics with JBVAMC R&D Office contact information on a regular basis.
6. The R&D Committee is responsible for evaluating the adequacy of the outreach activities annually and recommending changes as may be indicated. Evaluation consists of review of the patient questionnaires that are distributed after Research Week programs and individual patient outreach events. The Patient Outreach Coordinator tabulates results and prepares documentation for RDC review post-event.

REFERENCES

1. VHA Directive 2008-079 dated November 17, 2008
2. VHA Handbook 1200.05
3. Belmont Report “Ethical Principles & Guidelines of the Protection of Human Subjects of Research.

**REVISION LOG:
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Version (#, date)	Replaces (#, date)	Summary of changes
1.2; March 21, 2011	1.1; March 30, 2009	
1.3; July 13, 2011	1.2; March 21, 2011	Description of the evaluation process included