



# **Stratton VA Medical Center IRB Standard Operating Procedure: Outreach Program for Human Research Subjects**

## **PURPOSE**

To describe responsibilities and procedures for the active involvement of current, prospective or past research subjects, or their designated representatives and the conduct of outreach activities to human research subjects and their communities.

## **POLICY**

To comply with the ethical principal of respect for persons participating in research and to maximize their involvement in the research process and outreach activities.

## **RESPONSIBILITIES**

The Medical Center Director is responsible for establishment and oversight of all aspects of the Outreach Program for Human Research Subjects at the Stratton VA Medical Center.

The Associate Chief of Staff for Research and Development (ACOS/R&D) is responsible for implementation of outreach programs for human research subjects.

The Research Administrative Office is responsible for the participant outreach program of the Human Research Protection Program (HRPP).

The Research Compliance Officer (RCO) oversees and evaluates the outreach program.

## **PROCEDURES**

The Research Administrative office will partner with the Veterans Service Center (VSC) to organize information and activities presented at Outreach Events sponsored by the Stratton VA Medical Center. The Outreach Events include presentations to volunteer organizations, veteran's organizations and community groups. At the events, information will be provided to veterans with a balanced view of VA Research, to summarize veterans rights and welfare, to help veterans decide whether they should participate in research studies. The outreach activities provide an avenue for prospective and current participants to obtain answers to questions they may have about research, to voice concerns or complaints about research.

Research administrative staff can be contacted to answer questions and offer information to current, prospective or past research participants at the Stratton VA

Medical Center. Contact information will be made available through brochures, and in consent forms.

**Research Contact Brochures:** It is essential that we keep subjects and potential subjects well informed through outreach activities and the distribution of information designed to enhance their understanding of human research. In addition, informational materials and/or videos will be made accessible to human research subjects and their families in multiple locations throughout the Stratton VA Medical Center. In particular, the informational brochure, "Volunteering in Research – Here are some things you need to know," will be distributed in clinics, with informed consent forms and in CBOCs.

The Stratton VA Public Affairs department has a Speakers Bureau with a listing of topics that the community may request to have a speaker present at an organizational function. The ACOS/R and the AO/R are on the list for research-related topics.

The institutional Review Board (IRB) assures that research participants are provided with a research and patient advocate contact telephone number in each consent form to discuss questions regarding their rights and welfare, to address any question they may have, to voice concerns or complaints to someone other than research staff or to have a contact number in the event research staff is not available.

With each research informed consent form, principal investigators provide participants with a letter that they may return in a stamped envelop to Research Service if they wish to be contacted for an invitation to Research Day, usually held in the spring of each year. Also, with each informed consent form, subjects are asked to complete a satisfaction survey and return this in a stamped envelope to Research Service.

In addition to research participants, IRB members, HRPP staff, research staff, researchers, government officials, and Veteran Service Organization representatives are also invited to attend Research Day.

A satisfaction survey is handed to guests upon arrival. Research service considers the results of the survey, attendance information, investigator comments and feedback from incidental sources in evaluating and revising the Outreach efforts on at least an annual basis. The Administrative Officer Research (ARO) will submit a report to the Research and Development (R&D) Committee. The Research and Development (R & D) Committee, in turn, will be responsible for evaluating the adequacy of the outreach efforts and recommend changes if appropriate.