

Department of Veterans Affairs
Tuscaloosa VA Medical Center

Human Research Protection Program SOP # 14

May 7, 2007

PARTICIPANT OUTREACH

1. POLICY

The Tuscaloosa VA Medical Center (TVAMC) Human Research Protection Program (HRPP) is committed to providing information to potential research participants about ongoing research activities, providing information about their rights to volunteer for or decline participation in a research study, and to address questions, concerns, or complaints of research participants.

It is the policy of the TVAMC HRPP to ensure that potential research participants receive educational materials about participation in research activities and that the TVAMC HRPP responds to the concerns of research participants. This standard operating procedure (SOP) establishes procedures that ensure the distribution of outreach materials to the potential research participant and to provide a procedure for research participants to ask questions and voice concerns or complaints.

2. RESPONSIBILITIES

Every VHA employee must comply with all applicable Local, State and Federal laws when distributing information about research activities and participation. Only materials that are reviewed and approved by the TVAMC Institutional Review Board (IRB) may be distributed to current, prospective, or past research participants or their designated representative.

TVAMC Institutional Review Board (IRB) is responsible for the review and approval of all outreach materials and educational information that are distributed to potential research participants. The TVAMC IRB is responsible for ensuring that each protocol or consent form involving prospective human subjects provides a procedure for research participants to ask questions and voice concerns or complaints to the investigator or the IRB office.

The Coordinator of Research and Development is responsible for the orchestration of a program of activities to ensure respect for human participants, outreach to participants and communities, and appropriate responses to questions, concerns and complaints.

The Research and Development Committee is responsible for a annual review of participant outreach activities and responsible for making recommendations of changes to enhance outreach.

Investigators are responsible for maintaining respectful interactions with participants, involving research participants at every stage, enhancing appropriate safeguards, answering questions in a

complete and sensitive manner, and participating in outreach and educational activities to participants and their communities. The investigators are responsible for submitting the materials and obtaining IRB approval prior to distributing outreach materials and educational information to potential research participants. The investigator must provide a written description of a procedure for research participants to ask questions and voice concerns or complaints to the investigator or IRB office.

The IRB Office Staff will maintain an information sheet that will be posted in various public locations in the TVAMC, including the TVAMC patient education office, research office area, and in the office of the TVAMC Patient Representative. This information sheet explains how to contact the HRPP staff in regards to questions, concerns or complaints about the research and whom to contact when the HRPP staff cannot be reached. The IRB Office Staff will follow the procedures below in regard to handling questions, concerns or complaints about research.

3. DEFINITIONS

- a. **Outreach Materials** consist of any media forms (e.g., pamphlets, brochures, or flyers) that provide research participants with education or information regarding research involving human participants.
- b. **Contact Information for questions, concerns, or complaints** consists of the current name, location and contact number of the IRB office, IRB Chair, Coordinator or Research and Development, R&D chair, Administrative Officer of Research and Development (if position filled), and/or Patient Representative (i.e. in HRPP posted notice and/or consent forms) . This contact information should also include the name, location, and contact number of the principal investigator when applicable (i.e. in consent forms).

4. PROCEDURES

- a. **Outreach Opportunities:** The TVAMC HRPP conducts activities and offers educational opportunities to participants, prospective participants, or their community that are designed to enhance their understanding of human research.

These activities include (however, are not limited to):

- The distribution of IRB-approved pamphlets, brochures, or flyers
- The availability of VA-sponsored educational videos
- The sponsorship of a booth at the annual TVAMC Patient Education Fair
- The sponsorship of continuing education programs for the TVAMC staff who interact with current and prospective research participants
- Community speaking engagements or outreach activities in the community
- Involvement of community members on the IRB
- Public activities during the annual VA Research Week

Outreach materials are required to be submitted by the investigator or other HRPP staff member to the IRB for review and approval prior to distribution. Examples of outreach materials used at the TVAMC and the community are:

- “Should I Participate in a Clinical Study?”
<http://www.research.va.gov/programs/pride/veterans/default.cfm>
- Video (8-minute) designed for patients; it is a companion to the above brochure/handout
<http://www.research.va.gov/programs/pride/veterans/default.cfm>
- “Men and Depression” from the National Institute of Mental Health
- Flyers and letters to veterans listing or describing research studies
- Tuscaloosa VA Medical Center “QuickCard Survey.”

These outreach materials are made available in the TVAMC waiting rooms, TVAMC patient education rooms, and community veteran organizations.

- b. **Periodic Evaluation and Improvements of Outreach Activities:** The TVAMC HRPP periodically evaluates its outreach activities and makes changes when appropriate. An annual report of Participant Outreach activities is periodically reported to the R&D committee. The R&D Committee recommends changes when needed and these changes are implemented by the Coordinator of Research and Development or other assigned HRPP staff. The evaluation may include a summary of activities over the previous year, attendance rosters for events, evaluation forms following events, customer satisfaction surveys, surveys of the informed consent/recruitment process, or other activities.
- c. **Questions, Concerns, or Complaints:** The TVAMC HRPP requires that each protocol that involves human participants provide a procedure for research participants to ask questions and voice concerns or complaints to the investigator or the IRB office. This information may be included in the informed consent form (SOP #7). The information should include instructions on how to contact the investigator, research staff, or IRB office in regards to questions, concerns, or complaints about the research. The informed consent should also include information on research-related injury (i.e. when medical treatments are available, whom to contact) and whom to contact with questions about their rights as a research participant (See SOP #7). The IRB office staff, member or chair (i.e. an informed individual who is unaffiliated with the specific research protocol) will be available to discuss the questions, concerns or complaints about the research in a safe and confidential setting (i.e. private office) and provide a reliable channel for current, prospective, or past research participants or their designated representatives to discuss problems, concern, or questions; obtain information; or offer input. The HRPP staff are also available to the VA Patient Representative, who may often be the first point of contact for a current, prospective, or past research participants/designated representative who has a question, concern or complaints about research. Complaints or allegations of noncompliance are directed to the Chair of the IRB and Coordinator of Research and Development and the policies or procedures for handling such complaints or allegations are outlined in SOP #18.

5. REFERENCES

- VHA Handbook 1200.5
- <http://www.research.va.gov/programs/pride/veterans/default.cfm>

6. ATTACHMENTS

- “Should I Participate in a Clinical Study?”
<http://www.research.va.gov/programs/pride/veterans/default.cfm>
- Research flyer explaining how to contact the HRPP staff in regards to questions, concerns or complaints about the research and whom to contact when the research staff cannot be reached.

7. RESCISSIONS

IRB Standard Operating Procedures dated July 1, 2004.

8. REVIEW DATE

January 1, 2012

Signature on file in R&D Office

Lori L. Davis, MD

Coordinator of Research and Development