

DEPARTMENT OF VETERANS AFFAIRS
Harry S. Truman Memorial Veterans' Hospital
800 Hospital Drive
Columbia, Missouri

HPM 589A4-366
April 20, 2006
Issued by: Research

OUTREACH PROGRAM FOR HUMAN RESEARCH PARTICIPANTS

1. **PURPOSE:** To describe responsibilities and procedures for the active involvement of research participants in protocols and the conduct of outreach activities to human research participants and their communities.

2. **POLICY:** To comply with the ethical principal of respect for persons participating in research and to maximize their involvement in the research process, including proactive outreach activities.

3. **RESPONSIBILITIES:**

a. The Hospital Director is responsible for oversight of all aspects of the Research Program at the Harry S. Truman Memorial Veterans' Hospital (HSTMVH).

b. The Associate Chief of Staff for Research and Development (ACOS/R&D) is responsible for the orchestration of a program of activities to ensure respect for human participants, involvement in protocols, and outreach to communities.

c. The Human Research Compliance Officer (HRCO) is responsible for the day-to-day assurance of compliance with all aspects of the Human Research Protection Program (HRPP), including participant outreach activities.

d. Investigators involved in human research protocols 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.

4. **PROCEDURE:**

a. The consent materials for each protocol will be reviewed by the HRCO to ensure that procedures are in place to facilitate the ability of research participants to ask questions, express concerns, or voice complaints to the investigator.

b. The HRCO will distribute a Human Research Participant Pamphlet which provides information regarding a safe, confidential, and reliable channel for current, prospective, or past research participants (or their designated representatives) to discuss concerns, raise questions, obtain information, or offer input to an informed individual who is unaffiliated with the specific research protocol. The pamphlet will be disseminated by investigators to all persons who are approached to consent to participate in a human research protocol. In addition, the information available in the pamphlet will be posted on the internet site for the Harry S. Truman Memorial Veterans' Hospital.

c. The HRCO will organize outreach programs for human research participants and their communities; these outreach activities will include presentations to volunteer organizations, veterans service organizations, and community groups. In addition, informational materials and/or videos will be made accessible to human research participants and their families in conspicuous locations throughout the HSTMVH.

d. On an annual basis, the HRCO will submit a report to the Research and Development (R&D) Committee on outreach activities that have been conducted for human research participants and their communities. The R&D Committee, in turn, will be responsible for evaluating the adequacy of the outreach activities and recommending changes as may be indicated.

5. **FOLLOW-UP RESPONSIBILITY:** The ACOS/R&D is responsible for the follow-up of this HPM.

6. **RECISSIONS:** None.

APPROVED:

MARIE L. WELDON, FACHE
Acting Director