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

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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 Medical Center Director is responsible for a Research Participant Outreach Program that includes:

(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.

(2) Availability of 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 as reasonably possible 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.

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

(5) Ensuring that recruiting documents, flyers, and advertisements for non-VA research are not posted within or on the premises of the VA facility.

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

(1) Implementing the local Research Participant Outreach Program.

(2) Ensuring that local investigators have an adequate supply of the brochure "Volunteering in Research – Here are some things you need to know."

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

d. Investigators involved in human research protocols are responsible for making every reasonable effort to make 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 (or surrogate when necessary) when an individual is approached to take part in a project. This does not apply when informed consent has been waived. 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 research staff, and/or the participant wishes 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, and to ensure their ability to render proper assistance to potential subjects.

4. **PROCEDURE:**

a. The informational brochure "Volunteering in Research – Here are some things you need to know" will be available in settings where research subjects may be recruited. This brochure will also be available in the Harry S. Truman Memorial Veterans' Hospital (Truman VA) Research Service office and will be distributed to human subject principal investigators to whom this policy applies.

b. The consent materials for each protocol will be reviewed by the RCO to ensure that the consent document(s) contain reliable contact information for both study staff and an individual independent of the study team. The RCO will also be a resource for investigators and other study staff to communicate relevant details of the study when participants concerns or questions are raised.

c. Information about the Truman VA Human Research Protection Program is available on the Truman VA Research Service internet site. This site includes contact information for the Truman VA and the Health Sciences Institutional Review Board (HS-IRB).

d. The ACOS/R&D in collaboration with the RCO will organize outreach programs for human research participants and their communities; these outreach activities may include presentations to volunteer organizations, veterans service organizations, VA Research Week activities, and community groups. In addition, informational materials and/or videos will be made accessible to human research participants and their families in locations throughout the Truman VA.

e. On an annual basis, the ACOS, R&D 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.

f. When a question, concern, or problem is identified by a research subject or prospective subject the ACOS, R&D and the RCO will be notified, if not otherwise the point of contact. The ACOS, R&D or RCO will discuss the matter with the research subject and complete a Report of Contact if warranted. Queries about the legitimacy or existence of a protocol from a prospective subject who may have been contacted via a recruitment mechanism may not warrant a report of contact. Other concerns voiced by a research subject or prospective subject will be investigated thoroughly. This may include discussions with the Principal Investigator or other research personnel. If the investigation suggests concerns about subject safety, risk, privacy violations, or other related matters the issue will be brought to the attention of the IRB of record, Privacy Officer, Information Security Officer, the Facility Director, and others (as applicable). If warranted, a report will be forwarded to oversight bodies.

5. FOLLOW-UP RESPONSIBILITY: ACOS/R&D.

6. RECISSIONS: HPM 589A4-366 dated January 11, 2011.

REFERENCES:

VHA Handbook 1200.05 Requirements for the Protection of Human Subjects in Research dated October 15, 2010

APPROVED:

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