PARTICIPANT OUTREACH

1. POLICY

The Birmingham VA Medical Center (BVAMC) 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 BVAMC HRPP to ensure that potential research participants receive educational materials about participation in research activities and that the BVAMC 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 participants as needed 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 BVAMC Institutional Review Board (IRB) may be distributed to current, prospective, or past research participants or their designated representative.

BVAMC 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 BVAMC 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 Research Compliance Officer 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. This includes providing information about research in the patient education office, research office area, and in the office of the BVAMC Patient Representative.

The Research and Development Committee is responsible for an 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 by involving them at every stage of the research; enhancing appropriate safeguards, answering questions in a complete and sensitive manner, and if possible 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 delegates a member that subjects or prospective subjects can contact regarding questions, concerns or complaints about research and whom to contact for further information. The R&D Staff will follow the procedures below in regard to handling questions, concerns or complaints about research.

3. **DEFINITIONS**

   See HRPP SOP# 24 – HRPP Definitions

4. **PROCEDURES**

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

   These activities may 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 continuing education programs for the BVAMC staff who interact with current and prospective research subjects.
   - BVAMC speaking engagements or outreach activities within the hospital setting.
   - Involvement of community members on the IRB.
   - Public activities during 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 BVAMC and the community are:
   - “Should I Participate in a Clinical Study?”
   - Video (8-minute) designed for patients; it is a companion to the above brochure/handout
   - Flyers/Brochures about Research, outlining who to contact

   These outreach materials are made available in the BVAMC waiting rooms, BVAMC patient education rooms, and veteran community organizations.
b. **Periodic Evaluation and Improvements of Outreach Activities:** The BVAMC HRPP periodically evaluates its outreach activities and makes changes when appropriate. Activities are periodically reported to the R&D committee by Investigators or HRPP staff. The R&D Committee recommends changes when needed and these changes are implemented by 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 that have been conducted at the BVAMC.

c. **Questions, Concerns, or Complaints:** The BVAMC 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 designated member (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, IRB Administrator and/or Research Compliance Officer and the policies or procedures for handling such complaints or allegations are outlined in SOP #18.

5. **REFERENCES**

- VHA Handbook 1200.05 Requirements for the Protection of Human Subjects in Research

6. **ATTACHMENTS**

- “Should I Participate in a Clinical Study?”
- 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.
- Research flyer outlining what constitutes “Research Involving Human Use”
7. **RESCISSIONS**


8. **REVIEW DATE**

January 2021

[Signature]

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