

TITLE: Community Outreach

1.0 PURPOSE

This Standard Operating Procedure (SOP) sets forth the policies and procedures the VA Central IRB and the Program for Research Integrity Development and Education (PRIDE) follow in conducting and supporting community outreach efforts to investigators, research participants, the VA research community, and the local communities supported by VA medical facilities.

2.0 REVISION HISTORY

Date of Initial Approval	July 16, 2008
Revision Dates	March 25, 2010 August 26, 2010 August 10, 2011

3.0 SCOPE

This standard operating procedure applies to all VA Central IRB members, the VA Central IRB administrative staff, and the rest of the PRIDE staff.

4.0 POLICY

It is the policy of the VA Central IRB and PRIDE to promote and encourage community outreach efforts. This includes outreach efforts to investigators, human research participants, potential human research participant volunteers, the VA research community, and the public.

5.0 DEFINITIONS

See VA Central IRB SOP 128, Definitions Used in VA Central IRB SOPs.

6.0 RESPONSIBILITIES

6.1 VA Central IRB members are responsible for being knowledgeable of VA and other requirements for the protection of human research participants and for representing accurately the requirements of the VA Central IRB in their daily activities at their local facilities. VA Central IRB members may often serve as a knowledge resource for their local VA facility regarding the requirements of the VA Central IRB and for the protection of human research participants.

6.2 The VA Central IRB administrative staff is responsible for ensuring that outreach activities are conducted appropriately in accordance with this SOP.

6.3 PRIDE staff are responsible for assisting in the development of human research participant brochures, video tapes, web-based information materials,

research administration staff. PRIDE staff are also responsible for maintaining adequate supplies of outreach materials to distribute upon request and for assisting in answering the PRIDE toll free phone line and directing the calls as applicable.

7.0 PROCEDURES

7.1 Educational Materials and Programs

7.1.1 PRIDE, which the VA Central IRB is organizationally aligned under, develops and distributes a variety of educational materials for human research participants or potential participants. These are free and provided to local VA facilities and directly to Veterans and family members upon request.

7.1.1.1 The materials provide basic information about VA research and summarize the rights and welfare of human research participants. They cover such topics as what is a research project, are there risks and/or benefits in participating in a VA research project, what is informed consent, and what should an individual consider prior to making a decision to participate in a research project. These materials include the following:

- A brochure providing veterans a balanced view of VA research and summarizing the rights of human research participants and what they should know prior to making a decision to participate or not in VA research.
- A video providing the same information
- A poster designed for patient waiting areas and examination rooms that contains several questions veterans may want to ask before deciding whether or not to participate in a VA research project

7.1.1.2 The brochure, video, and poster are available in both English and Spanish and can be ordered from the on-line from the PRIDE website. PRIDE administrative staff members receive the orders via e-mail and ship requested materials out within a week of receipt of the order. A web friendly version of the brochure is also available. The video can also be viewed on-line, as can a transcript of the video.

7.1.2. PRIDE also develops and conducts educational programs for the VA research community to include VA leadership, research administrative staff, and investigators. These courses change from year to year based on the needs of the VA research program but generally the following courses are offered one or more times per year and contain the latest information concerning human research protection.

- Introductory and advanced courses for VA personnel involved in the administration of Human Research Protection Programs (HRPPs);

information is often presented about the VA Central IRB at these courses by PRIDE and/or VA Central IRB Administrative staff

- Local Accountability courses designed to keep the VA research community apprised of changes and new requirements regarding the management of HRPP programs within the VA.
- An update for the VA research community is presented at the annual conference of the Public Responsibility in Medicine and Research Conference (PRIM&R); this is also open to the rest of the PRIM&R attendees
- An VA IRB Chair meeting will be held on a biennial basis, bringing VA IRB Chairs together for both training and networking

7.1.3 The PRIDE and VA Central IRB staff also conduct periodic informational webinars for specific audiences as follows:

7.1.3.1 For investigators and their project team members who are new to the VA Central IRB research project application process. An overview is given on the general functions and operations of the VA Central IRB, the application process, and application requirements for the PI and participating sites. The PI and Local Site Investigator application forms are also reviewed. This is a very interactive webinar with significant time devoted to answering questions from the audience.

7.1.3.2 For VA Central IRB Local Site Liaisons. These are designed to provide an overview of the duties and responsibilities of VA Central IRB Liaisons and include instructions for using the VA Central IRB SharePoint site. These webinars are also used to obtain feedback from VA Central IRB Liaisons on any problems or concerns and to discuss how to continually improve communications.

7.1.3.3 For Local Site Officials. These are conducted to acquaint local site officials with the provisions of the Memorandum of Understanding entered into by VA Facilities with the VHA Central Office HRPP to use the VA Central IRB as an IRB of Record. Duties and responsibilities of each entity are reviewed and an overview is given concerning the operations of the VA Central IRB.

7.1.4 VA Central IRB staff and other members of PRIDE also participate in the annual Office of Research and Development Research Week activities. VA Central IRB administrative staff members and other PRIDE staff also participant upon request as invited guests or speakers at Research Week activities at local VA facilities. Staff members can also participate upon request in other local VA facility educational activities.

7.1.5 VA Central IRB Coordinators and/or the VA Central IRB Administrator attend project kick-off meetings to discuss ongoing monitoring of

approved projects by the VA Central IRB. VA Central IRB staff members also speak at local VA facility Research week activities upon invitation.

7.2 PRIDE and VA Central IRB Websites. PRIDE maintains a public website and the VA Central IRB maintains a page on this website.

7.2.1 The PRIDE home page contains information for investigators and local Research and Development administrative office personnel to assist them in ensuring the protection of human subjects. Information is available on upcoming conferences and other training opportunities, as well as the latest policy guidance. Links are provided to current regulatory guidance and VA policy. There is also a section for Veterans where they can view and order the brochure, video, and poster on "Volunteering in Research."

7.2.2 The VA Central IRB website also contains information for local Research and Development Offices and investigators. It contains a listing of VA facilities that have added the VA Central IRB as an IRB of Record to their Federalwide Assurance for use by investigators in the recruitment of sites to participate in multisite research; policies and procedures of the VA Central IRB; forms for download and use by investigators and local sites; information about the VA Central IRB membership; reporting requirements; frequently asked questions (FAQs); upcoming VA Central IRB meeting dates; and contact information for investigators, sites, human participants, and the public. The website is constantly changing and evolving to meet the needs of investigators, local VA sites participating in research overseen by the VA Central IRB, and members of the public interested in or who are participating in human subjects research overseen by the VA Central IRB.

7.3 Other Outreach Efforts

7.3.1 PRIDE maintains a toll free number for use by the VA research community and by human research participants. This number is answered by PRIDE staff during duty hours and has voice mail capability for after hours. This toll free number is listed on the VA Central IRB website and is included on all informed consent documents approved by the VA Central IRB.

7.3.2 The VA Central IRB also has its own e-mail address, vacentralirb@va.gov. This e-mail address is listed on the VA global system and is monitored on a daily basis by VA Central IRB staff.

7.3.3 Outreach efforts are evaluated during the VA Central IRB annual evaluation per VA Central IRB SOP 123, Evaluation of the VHA Central Office HRPP, as well as during field focus groups, conferences, and other training sessions where feedback is encouraged. Investigators, research project team members, VA research administrative staff at local facilities, and research participants are also encouraged to provide feedback throughout the year as a

tool for evaluating any needed improvements in the operations of the VA Central IRB.

7.4 Responding to Participant or Others Complaints, Questions, or Issues.

7.4.1 When receiving a call from a prospective, current, or former research participant, or from anyone else having a question, concern, or complaint, on the PRIDE toll free number, the person taking the call will log the details into the call log.

7.4.1.1 If the caller has a specific question about a particular research project, i.e., how to enroll or a question about what the research entails, the caller will be referred to the nearest local participating site points of contact for that study. The person logging in the call will follow-up in one week to ensure the caller received the information needed. If the question or issue pertains to general or administrative issues, it will be directed to the appropriate VA Central IRB Coordinator or PRIDE staff member. That person will be responsible for entering the resolution of the call on the call log.

7.4.1.2 If the call involves a complaint concerning a study for which the VA Central IRB is serving as an IRB of record, the matter will be immediately referred to the VA Central IRB Administrator. The call will then be handled in the manner described in paragraph 7.4.2.

7.4.2 Any complaint received, whether through the toll free line, in-person, by mail, or through e-mail, will be immediately referred to the VA Central IRB Administrator.

7.4.2.1 The VA Central IRB Administrator will determine whether the complaint or issue can be handled administratively by the VA Central IRB staff. If the matter can be handled administratively, the participant will be contacted with the resolution, and if the complainant is satisfied, the matter will be closed and reported as information at the next VA Central IRB meeting. The resolution of the issue will be documented in writing, either through a memorandum for the record or a letter to the complainant detailing the resolution. If the complainant is not satisfied, the matter will be referred to the VA Central IRB Co-Chair. If the matter still cannot be resolved, it will be forwarded to the VHA Central Office Human Protections Administrator for further review and investigation.

7.4.2.2 If the matter cannot be handled administratively, such as it involves allegations of non-compliance, misconduct, or the health and welfare of research participants or others, the matter will immediately be referred to one of the VA Central IRB Co-Chairs. If the issue involves non-compliance or the reporting of a serious adverse event, the matter will be handled in accordance with those applicable SOPs. If not, the Co-Chair will decide on a course of action. This can include but is not limited to:

- Referral to the convened VA Central IRB for review
- Referral to the VHA Central Office IO or HPA for review
- Referral to the PI/SC of the study or an LSI with appropriate follow-up

7.4.2.3 Once a resolution has been attained, the complainant will be informed either by letter or phone. E-mail will not be used. If the complainant is informed by phone and written memorandum of record will be made of the conversation.

7.4.3 The VA Central IRB Administrator will keep a file of all complaints by calendar year. Complaints not referred to the convened VA Central IRB will be reported to the next convened meeting after resolution as informational items.

7.5 Formation of Veteran Ad-Hoc Committees for Research Protocols

7.5.1. There may be special circumstances in which an ad-hoc committee will need to be formed to address issues involved in the review of a VA Central IRB protocol. The purpose of the ad-hoc committee would be to provide Veteran input on issues requiring Veteran input for a specific protocol and/or a specific issue.

7.5.2. A VA Central IRB Co-Chair or the convened VA Central IRB can request the formation of an ad-hoc committee composed of Veterans. The Office of General Counsel will be consulted to ensure that appropriate federal regulations and requirements regarding formation of committees involving non-federal employees are followed.

8.0 REFERENCES

8.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects

8.2 VHA Handbook 1200.5, Requirements for the Protection of Human Subjects in Research

I have reviewed and approved the content of this SOP.


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Date: 8/10/11