



## QUESTIONS & ANSWERS

# VA Central IRB

## VA Central Institutional Review Board

### What is the VA Central IRB?

The purpose of the VA Central IRB is to improve the lives of Veterans by enhancing the quality of human research protection in VA multi-site research projects. The VA Central IRB provides expert ethical and scientific review of multi-site projects while ensuring local issues are addressed. By enhancing the efficiency of IRB review for these projects, it also has the potential to facilitate faster translation of research results to advancements in health care.

### What are the advantages of using the VA Central IRB?

Research involving human subjects has changed dramatically since IRBs first came into existence several decades ago to review single-site projects. Advances such as the electronic medical record have paved the way for larger, more complex research projects involving multiple sites. Centralized IRB review ensures that these projects receive consistent expert ethical and scientific review.

Specific advantages of the VA Central IRB include:

- Centralized investigator accountability;
- Earlier identification of trends in adverse events;
- Elimination of concerns about local conflict of interest;
- Serving as a model for local IRBs for handling ethical issues in new areas of research (e.g., genomics medicine), developing policies and procedures, and other IRB issues;
- More efficient IRB review of multi-site projects; and
- The potential to facilitate faster translation of research results to advancements in clinical care.

### How does the VA Central IRB Operate?

The VA Central IRB reviews Veterans Health Administration (VHA), Office of Research and Development (ORD) projects. ORD determines whether or not a given project is a candidate for review by the VA Central IRB. Without cost to the local VA

facility, the VA Central IRB performs full, expedited, exempt, and continuing review, and provides waivers of HIPAA authorization as necessary and appropriate. It is staffed by the ORD Program for Research Integrity Development and Education (PRIDE), but VA Central IRB members and ad hoc ethical and scientific advisors are recruited from all over the country. The VA Central IRB meets monthly in person in Washington, D.C., and/or by video or teleconference.

### Who serves on the VA Central IRB?

The VA Central IRB is composed of approximately 20 voting members, including two co-chairs. Most members of the VA Central IRB are VA staff. Non-affiliated members have VA without-compensation (WOC) appointments. The current members are from 14 states, and have an average of 10 years experience with human subjects protection issues. Nine have been IRB chairs. Their backgrounds include extensive experience in science, medicine, nursing, pharmacy, and law, as well as the military and the clergy. There are five nonvoting members with expertise in ethical, regulatory and legal affairs, information security, and privacy. Ad hoc advisors are consulted as needed on issues outside the expertise of the voting and nonvoting members. Voting members serve three-year terms and may be reappointed. Co-chairs serve one-year terms.

### What measures are in place to ensure quality in the VA Central IRB review process?

Enhancing the quality of human research protection in VA-funded multi-site research projects is the primary purpose of the VA Central IRB. Measures that are or will be taken to ensure high quality in the VA Central IRB process include:

- Well-trained staff;
- Highly qualified IRB co-chairs and members;
- Expert ad hoc advisors;
- Formal peer-reviewed evaluation;
- Routine Office of Research Oversight (ORO) auditing and monitoring; and
- Association for the Accreditation of Human Research Protection Programs (AAHRPP) accreditation.



## Does the VA Central IRB need to be listed as a local IRB of Record?

Each local VA facility that intends to participate in projects that will be reviewed by the VA Central IRB must amend its Federalwide Assurance (FWA) to list the VA Central IRB as one of its IRBs of Record. It must also sign a Memorandum of Understanding (MOU) with the VHA Central Office. This MOU describes the respective roles and responsibilities of the local VA facility, the VHA Central Office, and the VA Central IRB. The Institutional Official (IO) of the VHA Central Office is the Principal Deputy Under Secretary for Health. The local IO is the medical center director.

## What are the local VA facility's responsibilities if the VA Central IRB is used?

Every VA facility has ultimate responsibility for its HRPP. Local roles and responsibilities include knowledge of the community culture, research culture, infrastructure, and state and local laws. The local VA facility also provides resources for the local HRPP; performs investigator oversight and local Research and Development (R&D) Committee review; documentation of training and credentialing of research team members; monitoring and auditing of projects; and local reporting of adverse events and unanticipated problems.

## What is the process for submitting a proposal to the VA Central IRB?

Once ORD determines that a project will be reviewed by the VA Central IRB, a two-step application process is initiated. In the first step the Principal Investigator (PI) or Study Chair (SC) submits a PI/SC application through the local Associate Chief of Staff for Research and Development (ACOS/R&D). This application includes model documents such as an informed consent form and recruitment ads or letters. The

PI also submits any waiver requests. Once the VA Central IRB approves the PI/SC application or requires only minor modifications for approval, the VA Central IRB determination letter to the PI and a copy of the PI/SC application package is sent to all VA facilities listed on the application as potential participating sites. The sites will have 30 days to provide comments.

Upon approval of the PI/SC application, or if only minor modifications are required, Local Site Investigator (LSI) applications are completed for all potential participating sites and submitted to the VA Central IRB through the PI/SC. The VA Central IRB then reviews the comments from the sites and determines if any changes are needed in the PI/SC application. The VA Central IRB is the final arbiter as to which comments require changes. The VA Central IRB then reviews the LSI applications and may also require changes in these.

Once both the PI/SC application and the LSI application for a participating site receive final approval from the VA Central IRB, the approved PI/SC and LSI application packages are sent to each specific site. Sites then make a final determination within 10 days as to whether they will participate or they can decline to participate. If they decide to participate, a copy of the VA Central IRB minutes is forwarded to the site. The project is then reviewed in accordance with local R&D Committee policies and the VA Central IRB is provided a copy of the site approval document for the study to begin at that site. Sites submitting a LSI application after the final approval of the PI/SC application are not afforded the 30-day comment period but are given the 10-day period to make a participation decision.

For more information about the VA Central IRB, please visit <http://www.research.va.gov/programs/pride/cirb>.