Veterans Health Administration
Research & Development
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QUESTIONS & ANSWERS

VA Central IRB

VA Central Institutional Review Board

What is the 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 will provide 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 clinical 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 will the VA Central IRB operate?

The VA Central IRB will review Veterans Health Administration (VHA) Office of Research and Development (ORD) projects. ORD will determine 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 will perform full, expedited, exempt, and continuing review, and it will provide waivers of HIPAA authorization. It will be staffed by the ORD Program for Research Integrity Development and Education (PRIDE), but IRB members and ad hoc ethical and scientific advisors will be recruited from all over the country. The VA Central IRB will be convened monthly to meet in person, or by video- or teleconference.

Who will serve on the VA Central IRB?

The VA Central IRB will be composed of approximately 20 voting members, including two co-chairs. Most members of the VA Central IRB will be VA staff. Non-affiliated members will have VA without-compensation (WOC) appointments. The current members are from 14 states, and have an average of approximately 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 six nonvoting members with expertise in ethical, regulatory and legal affairs, information security, and privacy. Ad hoc advisors will be consulted as needed on issues outside the expertise of the voting and nonvoting members. Voting members will serve 3-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 reveiw 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 being 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.

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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, the principal investigator (PI) will submit an application to the VA Central IRB through his/her Associate Chief of Staff for Research and Development (ACOS/R&D). The Local Site Investigator from each of the participating VA facilities will submit a Local Site Application through the local facility's ACOS/R&D.

The VA Central IRB will perform the review and send summaries of its considerations to all VA facilities that have submitted Local Site Applications. The local facility will have 30 days to provide comments to the Central IRB. The VA Central IRB will be the final arbiter as to which suggestions are addressed in the final version. Then the local VA facilities will make a final determination as to whether or not to participate in the project. The local Research and Development (R&D) Committee at each participating facility must approve the project before it is initiated at that facility.

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 Human Research Protection Program (HRPP). This MOU describes the respective roles and responsibilities of the local VA facility and the VHA Central Office HRPP. The Institutional Official (IO) of the VHA Central Office HRPP 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 that performs human research has ultimate responsibility for its HRPP, even if it uses an external IRB such as the VA Central IRB. Local roles and responsibilities include knowledge and communication regarding the local community culture, attitudes, research culture, and infrastructure, as well as the state and local laws. The local VA facility also is responsible for providing resources for the local Research Office and HRPP; providing investigator oversight and local R&D Committee review; maintaining documentation of training and credentialing of research team members; monitoring and auditing of projects; and local handling of adverse events and unanticipated problems.

Where can I get additional information?

For more information on VA Central IRB, please visit:

www.research.va.gov/programs/pride/cirb/