

QUERI Director

Office of Research and Development Service Directed Project: "The Cost and Benefits of the VA Central Institutional Review Board".

To whom it may concern

1. I am writing to ask you to assist Todd Wagner, PhD, in his project "The Cost and Benefits of the VA Central Institutional Review Board (CIRB)". This project is important to the VA Office of Research and Development (ORD), which is providing funding. More importantly, by examining the functioning and impact of the CIRB, we hope to improve the CIRB process and build support for it, both of which may directly benefit the research community.
2. You are getting this letter because you or an investigator in your center is the principal investigator for a multi-center project that was either a) reviewed by the CIRB (cases) or b) was reviewed by local IRBs (controls).
3. Background: The ORD Program for Research Integrity Development and Education (PRIDE), which administers the CIRB, requested this independent evaluation of the CIRB implementation. This project will evaluate the effectiveness of a Central IRB in terms of providing optimal protection for human research subjects and will explore the cost effectiveness, timeliness, and efficiency of centralized versus decentralized IRB review. The key objective is to determine whether there is potential for the protection of human research subjects to be enhanced by a central review and whether this is a cost effective and efficient model of IRB review.
4. The aims of this project are to:
 - a) Determine the cost effectiveness of a central IRB performing protocol reviews for multi-site projects as opposed to reviews by local site IRBs or affiliate university IRBs. This includes full, expedited, exempt, and continuing review processes.
 - b) Calculate and compare initial protocol review times for all review processes for the VA Central IRB versus the multiple IRB review. This should include the development of an average turnaround time for each process, from the time of protocol submission by the investigator to the time that a final decision is rendered covering all involved sites.
 - c) Assess the satisfaction level of investigators using the VA Central IRB as opposed to investigators submitting their proposals to the IRBs of all participating sites.
 - d) Assess the satisfaction level of local facilities in terms of the following:
 - Was local context adequately addressed?
 - Quality and timeliness of VA Central IRB interactions with local facility officials to include protocol processing, handling of adverse events, and investigator noncompliance

- e) Assess the level of local accountability maintained by the local facilities for their human research protection program including:
- Facility adherence with local facility/VA Central IRB MOU responsibilities to include training, credentialing, auditing, monitoring, reporting, and other requirements (e.g., R&D Committee review)
 - Local handling of adverse events
 - Providing appropriate input to the VA Central IRB in a timely manner on issues such as the local research culture and infrastructure; state and local laws, and investigator oversight
5. Your participation is critical to producing a valid and useful evaluation of the Central IRB implementation. Thank you in advance for taking time from your busy schedules to help provide information to the researchers conducting this study. We are committed to working with PRIDE to make sure lessons from this evaluation are used to improve the CIRB process.