Information for Research Compliance Officers

VA Central IRB
VA Institutional Review Board for Multisite Studies

Research Compliance Officer (RCO) responsibilities regarding the VA Central IRB are essentially the same as for their local IRBs in regard to studies that are approved and overseen by the VA Central IRB as an IRB of Record for the RCO's site.

Section 1: Local Site RCO

1. Local RCOs should become familiar with the provisions of the local site's Memorandum of Understanding with the VHA Central Office for the use of the VA Central IRB as an IRB of Record for the site.
2. RCO audits for studies overseen by the VA Central IRB should be conducted in the same manner as for the local IRB with the results communicated as follows:
    a. All reports of apparent serious noncompliance should be submitted directly to the VA Central IRB via either the VA Central IRB Manager assigned to the study or the VA Central IRB Administrator. All reports should clearly identify if apparent or serious noncompliance is being reported by indicating this in the findings section or at the beginning of the report.
    b. Copies of routine regulatory and informed consent audit reports that do not require immediate review and/or action by the VA Central IRB will be submitted by the local study teams at the time of continuing review.
3. If a local site's SOPs require that an RCO submit other types of reports to the VA Central IRB for review, these may be submitted to the VA Central IRB Network Director. An explanation of why the document is being submitted should also be included. If the report pertains to a specific study, the report may also be submitted to the VA Central IRB Manger for that study if known.
4. Local RCOs may be asked to conduct audits or perform other functions, such as observing the informed consent process, by the VA Central IRB in regard to the studies it oversees. The VA Central IRB may request an audit or action be completed due, but not limited to, cases of serious or continuing non-compliance, concerns about the consenting process or documentation requirements, or if there is a complicated study design or inexperienced study teams. Audits can be as narrow or as broad as the IRB needs in order to address any human subject protection concerns and are often required by the IRB as part of a corrective action plan.

Section 2: VA Central IRB

1. The VA Central IRB will provide written determinations regarding the RCO audit reports or other reports it reviews as applicable, to the RCO, local sites, and local study teams in a timely manner.
2. The VA Central IRB will make available VA Central IRB records that are required in order for RCOs to carry out their local auditing and compliance functions.

3. RCOs will be included in invitations to VA Central IRB Liaison webinars and other educational programs conducted by the VA Central IRB for local sites.
4. The VA Central IRB will maintain copies of SOPs, forms, and other VA Central IRB-specific guidance on the VA Central IRB website for reference.

Section 3: IRBNet

Each RCO is granted access to IRBNet by their local Research Administration.

1. Project files that the VA Central IRB Local Site Liaison can access in IRBNet:
    - Project Documents: approved PI/SC and/or LSI Application, approved amendments, updates, and continuing review applications.
    - VA Central IRB Notifications: new notifications from the VA Central IRB to study teams and VA Central IRB Local Site Liaisons, such as requests for local site review.
    - Study Team Responses: used to submit responses, to include revised documents, to previous VA Central IRB correspondence.

NOTE: RCOs who also serve as VA Central IRB Liaisons should also reference the handout for Site Liaisons.

Contact the VA Central IRB at 877-254-3130 or at VACentralIRB@va.gov