

VA Central IRB Information Sheet RCOs



Research Compliance Officer (RCO) responsibilities regarding the VA Central IRB are essentially the same as for their local IRBs regarding 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. RCO audit reports with no findings or findings not required to be reported within a specified timeframe may be submitted by the RCO directly to the VA Central IRB using the IRBNet RCO Audit Workspace or the RCO may provide the report to the Investigator who will in turn submit the audit report to the VA Central IRB as part of the study continuing review application or, if continuing review approval is not required for a project, as part of an annual status report, or at project closure.
 - b. RCO audits that have findings of Apparent Serious or Continuing Noncompliance or Unanticipated Problem Involving Risks to Subjects or Others will be submitted by the RCO to the Investigator who will in turn submit the audit report and Form 124 Reportable Events to the VA Central IRB as part of a Reportable Event Package in IRBNet. Alternatively, RCOs may submit findings of these reportable events by email to the Investigator with the VA Central IRB included using VACentralIRB@va.gov. In the email, the RCO is requested to remind the Investigator of the prompt reporting timeframe and to submit the findings as a Reportable Event Package in IRBNet with Form 124 Reportable Events.
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 using the Common email: VACentralIRB@va.gov. An explanation of why the document is being submitted should also be included. If the report pertains to a specific study, please reference the study number and preferably the IRBNet project number in the correspondence.
4. Local RCOs may be asked by the VA Central IRB to conduct audits or perform other functions, such as observing the informed consent process, on studies the IRB 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 team. Audits can be as narrow or as broad as the IRB needs to address any human subject protection concerns and may be 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, and within IRBNet in a timely manner.
2. 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.
3. 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 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