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Please follow the instructions below when submitting a PI/SC Request for Exemption and the LSI exempt project(s) to the VA Central IRB (CIRB).

IMPORTANT NOTE: The Common Rule Cooperative Studies requirements for single IRB review only apply to non-exempt research. However, ORD Funded Multi-Site Exempt Research may be submitted to the VA CIRB for efficiency. The VA CIRB will review the PI/SC Request for Exemption along with the central PO and ISSO. When multi-site exempt research is submitted and reviewed through the VA CIRB, there is no need for redundant local research administration approvals, including local PO or ISSO approval.

SUBMISSION INSTRUCTIONS FOR PI/SC

The forms listed below are required, when applicable, as part of the PI/SC Request for Exemption submission:

- Project Cover Sheet – *IRBNet Wizard*
- IRB Information Sheet – *IRBNet Wizard*
- Form 105: Request for Exemption
- Form 102 – Local ACOS/R&D Review Supplement
- Protocol
- Enterprise Research Data Security Plan (ERDSP)
- CV/ Biosketches – Study team members in the Investigator Role
- COI Determination(s) – *do not submit the OGE Form 450*
- Form 103: Waiver of HIPAA Authorization – *if applicable*
- Form 10-0493: MODEL HIPAA Authorization Form – *if applicable*
- MODEL Information Sheet or Consent Scripts – *if applicable*

Follow the steps below to submit the PI/SC Request for Exemption in IRBNet:

Step 1: Log in to IRBNet and "Create a New Project." See separate instructions on *How to Create a New Project* if needed.

Step 2: Compile the submission in IRBNet and submit the project to your local research administration office. This will be package -1 in IRBNet. Ensure that your local research administration is aware that this is being routed to the VA CIRB.

NOTE: The local research administration should **not** be making the exemption determination or conducting the limited IRB review. The exemption determination or the limited IRB review will be completed by the VA CIRB which will include central PO and ISSO approval.

Step 3: After your local research administration review is complete, submit the project to the VA CIRB. There are 2 ways the project can be submitted to the VA CIRB:

    a) Local research administration submits package -1 on behalf of the Researcher to the VA CIRB.
    This option is best if all the documents that were reviewed locally are the same as the documents that need to be reviewed by the VA CIRB.
    or

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          b) Researcher creates and submits a <u>new package</u> within the <u>same project</u> (this would be package -2) to the VA CIRB.
This option is best if the local research office documents reviewed are different than the VA CIRB documents. This would ensure the VA CIRB does not receive local documents.

          NOTE: Whether **a)** or **b)** is followed, the package that is submitted to the VA CIRB should only include documents that are required by the VA CIRB (see above table).

Step 4:   VA CIRB will review the PI/SC Request for Exemption.

        NOTE: During the VA CIRB administrative review process revisions, clarification, or other requests may be made prior to the submission receiving IRB review. This process will occur utilizing IRBNet's "Unlock and Lock" function so that you can add, remove, or revise documents within the same package.

Step 5:   Based on the categories of exemption that the project falls under, the VA CIRB will:

          a) Make an Exempt Determination
          or
          b) Approve the Project as Exempt with Limited IRB Review

Step 6:   Follow your local R&D Committee policies to obtain final approvals at your local Research Administration.

Step 7:   After your local R&D approval is received, you may now share the project with the LSI's in IRBNet utilizing the "Multi-Site" function. See separate instructions *How to Share a Multi-Site Project in IRBNet* if needed.

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SUBMISSION INSTRUCTIONS FOR LSI

The forms listed below are required, when applicable, as part of the LSI exempt submission:

> - Project Cover Sheet – *IRBNet Wizard*
> - IRB Information Sheet – *IRBNet Wizard*
> - Enterprise Research Data Security Plan (ERDSP)
> - Form 102 – Local ACOS/R&D Review Supplement
> - COI Determination(s) – *do not submit the OGE Form 450*
> - CV/ Biosketches – Study team members in the Investigator Role
> - Local Information Sheet or Consent Scripts – *if applicable*

Ensure you answer the IRB Information Sheet questions as it applies to your site **NOT the overall project.*

Follow the steps below to submit the LSI New Project in IRBNet:

Step 1:   Log in to IRBNet and go to the project that was shared by the PI/SC.

        NOTE: If the PI/SC has not shared the project with the LSI in IRBNet contact them directly and request that they share the project utilizing the Multi-Site function. If you are still unable to access the project, contact

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the VA CIRB or IRBNet Support for assistance. Do **not** create a new project. It is important that the LSI project in IRBNet is directly linked to the PI/SC project.

Step 2: Once in the project enter the name of the LSI in the Principal Investigator field, upload submission documents, and submit the project to your local research administration office. This will be package -1 in IRBNet. Ensure that your local research administration is aware that this is being routed to the VA CIRB.

NOTE: The exemption determination or the limited IRB review will have already been done through the PI/SC application to the VA CIRB and there is no need for repeating these determinations or approvals for the project at the local research administration.

Step 3: After your local research administration review is complete, submit the project to the VA CIRB. There are 2 ways the project can be submitted to the VA CIRB:

a) Local research office submits package -1 on behalf of the Researcher to the VA CIRB. *This option is best if all the documents that were reviewed locally are the same as the documents that need to be reviewed by the VA CIRB.*
or

b) Researcher creates and submits a <u>new package</u> within the <u>same project</u> (this would be package -2) to the VA CIRB. *This option is best if the local research office documents reviewed are different than the VA CIRB documents. This would ensure the VA CIRB does not receive local documents.*

NOTE: Whether **a)** or **b)** is followed, the package that is submitted to the VA CIRB should only include documents that are required by the VA CIRB (see above table).

Step 4: The VA CIRB will review the LSI exempt project.

NOTE: During the VA CIRB administrative review process revisions, clarification, or other requests may be made prior to the submission receiving IRB review. This process will occur utilizing IRBNet's "Unlock and Lock" function so that you can add, remove, or revise documents within the same package.

Step 5: Once review is complete, the VA CIRB will acknowledge (not approve) the LSI's exempt project.

NOTE: Central ISSO approval is a condition of VA CIRB acknowledgement of the LSI exempt project. This will not need to be repeated locally.

Step 6: Follow your local R&D Committee policies to obtain final approvals at your local Research Administration.

VA Central IRB Contact Information:

Please contact the VA Central IRB staff at 1-877-254-3130 or VACentralIRB@va.gov with any questions or concerns regarding the submission process.