

Please follow the instructions below when submitting a PI/SC or LSI New Project to the VA CIRB. As of **March 15, 2021**, VA Central IRB will only accept study action submissions through IRBNet in the VAIRRS system. If you have not done so already, please register for your IRBNet account at gov.irbnet.org.

SUBMISSION INSTRUCTIONS FOR PI/SC

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

<ul style="list-style-type: none"> • Project Cover Sheet – <i>IRBNet Wizard</i> • IRB Information Sheet – <i>IRBNet Wizard</i> • Form 108 – PISC New Project Application • Form 102 – Local ACOS/ R&D Review Supplement • Form 112a – Waiver of Informed Consent • Form 112b – Waiver of Documentation of Informed Consent • Form 103 – Waiver of HIPAA Authorization • Protocol • MODEL Informed Consent Form or Combined Informed Consent/HIPAA Form • Form 10-0493 – MODEL HIPAA Authorization Form • Enterprise Research Data Security Plan (ERDSP) • CV/ Biosketches – Study Teams in the Investigator Role • COI Determination(s) – Do not submit the OGE Form 450 	<ul style="list-style-type: none"> • Other Documents: <ul style="list-style-type: none"> ○ Form 110 series – Vulnerable Population Form (Pregnant Women/Prisoner) ○ Investigator’s Drug Brochure/Device Information ○ MODEL Recruitment Material/Phone Scripts ○ Survey/Questionnaires
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Follow the steps below to submit the **PI/SC** New Project 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.
- 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
 - b) Researcher creates and submits a new package within the same project (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 new 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: After final VA CIRB approval is received, follow your local R&D Committee policies to obtain final approvals at your local Research Administration.

Step 6: 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.

SUBMISSION INSTRUCTIONS FOR LSI

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

<ul style="list-style-type: none"> • Project Cover Sheet – <i>IRBNet Wizard</i> • IRB Information Sheet – <i>IRBNet Wizard*</i> • Form 104 – LSI Application • Form 102 – Local ACOS/ R&D Review Supplement • Site Specific Informed Consent Form or Combined Informed Consent/HIPAA Form • Form 10-0493 – Site-Specific HIPAA Authorization Form • Enterprise Research Data Security Plan (ERDSP) • CV/ Biosketches – Local Study Team Members in the Investigator Role • COI Determination(s) – Local Study Team Members in the Investigator Role - Do not submit the OGE Form 450 	<ul style="list-style-type: none"> • Other Documents: <ul style="list-style-type: none"> ○ Local Recruitment Material/Phone Scripts ○ Local Request for Waivers (Form 112a, Form 112b, Form 103 – ONLY when PI/SC Waiver does not apply. For example, accessing data in a site specific database)
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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 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.

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- 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.
- 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 new package within the same project (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 LSI new 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:** After final VA CIRB approval is received, 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.