



The instructions below should be followed when submitting a Principal Investigator (PI) or Local Site Investigator (LSI) New Project to the VA Central IRB (CIRB). Please contact the VA Central IRB staff at 1-877-254-3130 or VACentralIRB@va.gov with any questions or requests for support regarding the submission process.

SUBMISSION INSTRUCTIONS FOR PI

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

<ul style="list-style-type: none"> • Project Cover Sheet – <i>IRBNet Wizard</i> • IRB Information Sheet – <i>IRBNet Wizard</i> • Study Team Tracking Sheet – <i>IRBNet Wizard</i> • Form 100 <i>or</i> 101 – Protocol Template • Form 102 – Local ACOS/R&D Review • Form 103 – Waiver of HIPAA Authorization • Form 112a – Waiver of Informed Consent • Form 112b – Waiver of Documentation of Informed Consent • MODEL Informed Consent Form or Combined Informed Consent/HIPAA Form • MODEL HIPAA Authorization Form 10-0493 • Enterprise Research Data Security Plan (ERDSP) • CV/ Biosketches – Those in an Investigator role • COI Management Plan(s) 	<ul style="list-style-type: none"> • Other Documents: <ul style="list-style-type: none"> ○ Investigator’s Drug Brochure/Device Information ○ MODEL Recruitment Materials/Phone Scripts ○ Survey/Questionnaires
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Follow the steps below to submit the PI 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 ideal 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 (e.g., package - 2) to the VA CIRB.

This option is ideal 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 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. When revising an existing document in IRBNet, you should use the 'Update this Document' feature to maintain version control and history.

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:

Table with 2 columns listing required forms: Project Cover Sheet, IRB Information Sheet, Study Team Tracking Sheet, Form 102, Form 104, Local Informed Consent Form, Local HIPAA Authorization Form, ERDSP, CV/Biosketches, COI Management Plan(s), and Other Documents (Local Recruitment Materials, Local Waiver, etc.).

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.

NOTE: If the PI 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 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 ideal 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 (e.g., package - 2) to the VA CIRB.
This option is ideal 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. When revising an existing document in IRBNet, you should use the “Update this Document” feature to maintain version control and history.
- 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.