

IRBNet provides many tools for managing multisite research. The collaborative platform may network many sites that use a common protocol. Advantages include: elimination of redundant activities, streamlined oversight and access to critical project documentation, linked reporting capabilities, networked communication, and a more efficient, transparent process. Here are some instructions for successfully managing multisite research on IRBNet.

Multi-Site Litmus Test

The only time the IRBNet multi-site tool should be used is when there is research on a single protocol being conducted by independent PIs at different sites, each requiring a separate and distinct review by the committee of record.

If all of these criteria are not met, then it is not considered a multi-site project.

Definitions

Lead Site

A Lead Site reviews the protocol and core documents submitted by a Principal Investigator (with identified local project owners at *Local Sites*).

When complete, the approved documentation is referenced by all local research sites

Lead Site Project

This Project is the master project for the multi-site research. It contains the core protocol information, master consent template and other common project documentation.

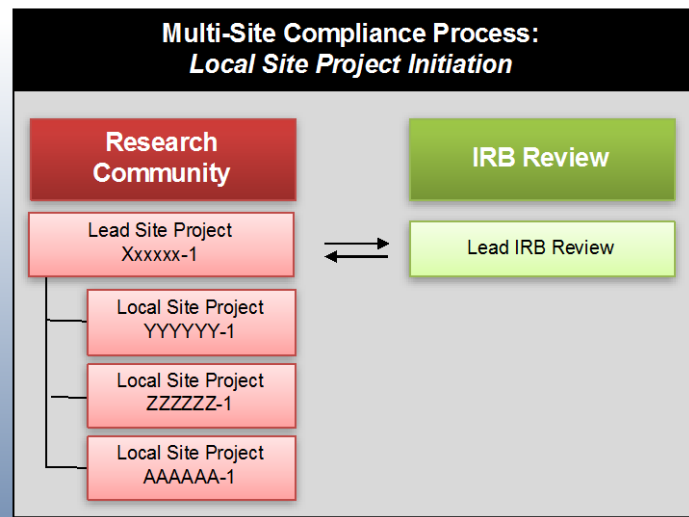
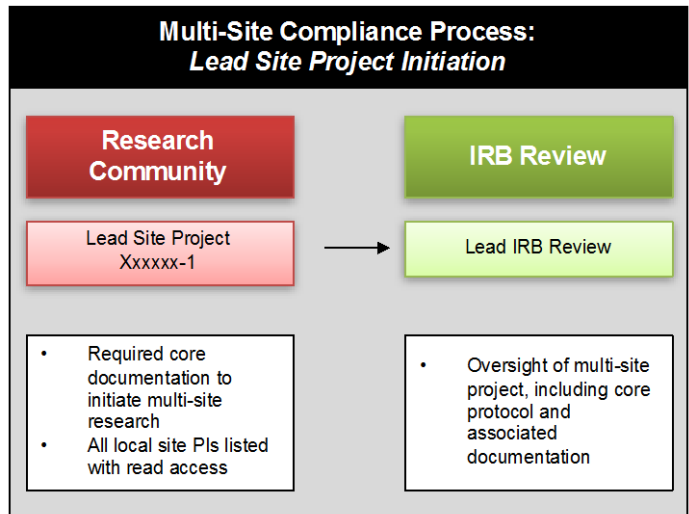
Local Site

An unlimited number of sites conduct their research using the approved Lead Site documents, together with local documentation.

Local Site document examples include: local consent forms, PI CVs, etc.

Local Sites vary in their requirements for review documentation, as per SOP.

Only one (1) Local Site may be in the same location (Research Organization) as the Lead Site.



Note: if you need more than one local site listed at a given research institution, please contact Support.

How to Create a Project for Initial Submission to a Lead Site

- ✓ Follow the 5 Steps of the Researcher to create the Lead Site project and submit to the lead committee. (5 Steps: Create, Design, Share, Sign, Submit)
 - When sharing with the Local Site collaborators/project owners/PIs, always select from their local research institution.
- ✓ The important difference is that the Lead Site is for core project documentation that will be referenced at all the Local Sites conducting research.
- ✓ All core project documentation belongs in the Lead Site Project, for reference by all Local Sites conducting research.
- ✓ DO NOT include local site documentation for review in this package.
- ✓ The Lead Site project should be shared with the coordinating researcher at each Local Site.

Establish your multi-site project at Local Sites.

Once the Lead Site Project is approved, you may begin the multi site process.

- ✓ Access the Share Project page to multi-site the project.
- ✓ The Lead Site project should be shared with the coordinating researcher at each Local Site

Establish multi-site projects at Local Sites

Once the Lead Site Project is approved, you may begin the multi site process.

IRENet User	Organization	Access Type
John Researcher	Metropolitan University, Frederick, MD	Full
Victor Hugo	North American College, Vivianville, IA	Read
Mark Jones	Gotham University, Frederick MD	Read

Share the lead site project using the multi-site tool.

From the Share Project page, select Multi-site.

Share the Lead Site Project Using the Multi-Site Tool

From the Share Project page, select Multi-site.

The screenshot shows the 'Share Project' page for a project titled '[44381-1] Motivations of Research Subjects: A Mixed Methods Study'. A red circle highlights the 'Share Project' button in the top right. A yellow box highlights the 'Multi-site' option in the list of sharing methods, with a checkmark and the text 'Select the Multi-site option.' A table at the bottom lists users with their organizations and access types.

User Name	Organization	Access Type
Victor Hugo	North American College, Wellsville, IA	Read
Mark Jones	Gotham University, Frederick MD	Read

Select a Local Site.

Find the appropriate Local Site with which you will be sharing Lead Site project information.

- ✓ You may select a location only once.
- ✓ Find the appropriate organization by using the Search tool.
- ✓ Once you have highlighted the correct organization, click to continue.

NOTE: To have new local sites (organizations) added in IRBNet and properly associated with your IRB, please contact IRBNet Support. Once they are established within IRBNet, we advise adding the organizations to your list of Authorized Organizations with access to your Documents for Researchers Library.

Select a Local Site

Find the appropriate Local Site with which you will be sharing Lead Site project information.

The screenshot shows the 'Select a Local Site' page. A yellow box highlights the search bar with the text 'Find the appropriate organization by using the Search tool.' A red circle highlights the 'Search' button. Another yellow box highlights the 'Select Organization' button with the text 'Once you have highlighted the correct organization, click to continue.' The search results show 'North American College, Wellsville, IA' selected.

Select a Local Site coordinator.

Each Local Site project must have a researcher designated as the coordinator; this is the Project Owner for this site.

- ✓ Use the drop-down menu to select the appropriate researcher.
- ✓ Add any message you would like to include with the automatic notification and click Save.

Select A Local Site Coordinator

Each Local Site project must have a researcher designated as the coordinator; this the Project Owner for this site.

Complete multi-site sharing.

Repeat the process until all Local Sites have access. The Project Overview page will display each site, along with its status.

- ✓ NOTE: If the Lead Site is also Local Site, it should be shared as such.
- ✓ Access detailed information for any of the sites associated with the multi-site project.

Complete Multi-Site Sharing

Repeat the process until all Local Sites have access. The Project Overview page will display each site, along with its status.

IRBNet User	Organization	Access Type
John Researcher	Metropolitan University, Frederick, MD	Full
Victor Hugo	North American College, Wellsville, IA	Read
Mark Jones	Gotham University, Frederick MD	Read

Lead Site	Site	Principal Investigator	Project Coordinator	Status	Reviewing Committee	Details
Yes	Metropolitan University, Frederick, MD	Researcher	Researcher	Approved	Metropolitan IRB	Details
No	Gotham University, Frederick, MD	Jones	Not submitted	-	-	Details
No	Metropolitan University, Frederick, MD	Researcher	Not submitted	-	-	Details
No	North American College, Wellsville, IA	Hugo	Not submitted	-	-	Details

Local Sites proceed normally with research on IRBNet.

Once each Local Site is established, they may submit local documentation to their local committee.

- ✓ The PI field will initially be blank. To enter a PI, click the Edit link.
- ✓ Be sure to add only the required Local Site documents in the Designer for Local Site projects.
- ✓ Each Local Site should walk through the 5 Steps of the Researcher to submit to their local committee.

Local Sites Proceed Normally

Once each Local Site is established, they may submit local documentation to their local committee.

Monitor the progress of other sites.

Once the multi-site project is assembled, researchers and committees associated with each Local Site will have visibility into Lead Site project documents, as well as all other sites.

- ✓ Researchers, committee administrators, and reviewers can all access Lead Site documentation via the Project Overview page.

Monitor the Progress of Other Sites

Once the multi-site project is assembled, researchers and committees associated with each Local Site will have visibility into Lead Site project documents, as well as all other sites.

Review Lead Site documentation.

You may review the Lead Site core documentation (Designer) and board documents (Reviews) at any time.

- ✓ View the Lead Site's submitted project documentation from the Designer page.
- ✓ View the Lead Site approval letter.

Review Lead Site Documentation.

You may review the Lead Site core documentation (Designer) and board documents (Reviews) at any time.

The screenshot shows the IRBNet interface for a project titled "[44381-1] Motivations of Research Subjects: A Mixed Methods Study" at the Metropolitan IRB, Frederick, MD. The "Reviews" section contains a table with one entry: a submission dated 04/05/2011, reviewed by the Full Committee, with an approved status and an expiration date of 04/04/2012. The "Board Documents" section contains a table with one entry: an approval letter dated 04/11/2011. Red callouts point to the "Reviews" and "Board Documents" sections, and the "Send Project Mail" option in the left sidebar.

Communicate with research teams.

You can communicate with researchers associated with any site by using the Send Project Mail tool.

- ✓ Choose between researchers associated with all sites, or only those with access to the Lead Site project.
- ✓ Message the coordinating researcher for each Local Site to inform them of changes to the Lead Site documentation.

Communicate with Research Teams

You can communicate with researchers associated with any site by using the Send Project Mail tool.

The screenshot shows the "Send Project Mail" tool in IRBNet. It displays a list of researchers associated with the project, including their names, organizations, and email addresses. A "Send Mail" button is visible next to each researcher. A red callout points to the "Send Project Mail" option in the left sidebar. Another red callout points to the "Send Mail" button for a specific researcher. A third red callout points to the "New Project Message" button at the top right. A fourth red callout points to the "Send Mail" button for the coordinating researcher. A preview of the email message is shown at the bottom, with the subject "IRBNet message from John Researcher" and the body text "Please login to IRBNet to review this project." and "Regards, John Researcher".

Ongoing Reporting to Boards

Update Lead Site core documentation and report events to Lead or Local IRBs via subsequent packages.

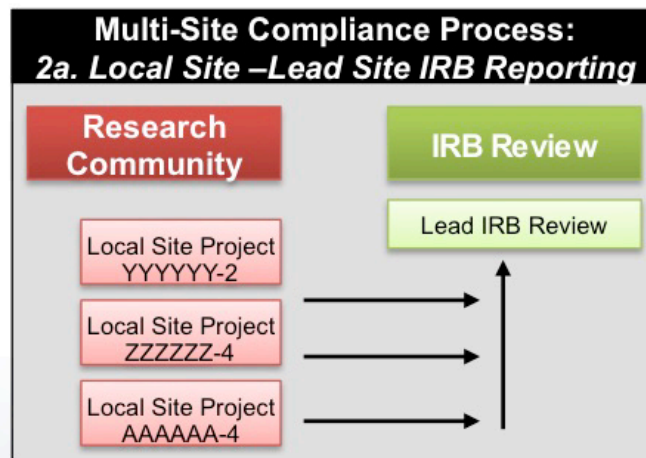
1. Lead Site Reporting to Lead IRB

Over time there will be the need for the Lead Site to update core project documents and circulate other documentation. The Lead Site Principal Investigator can create new submission packages and submit to the Lead IRB as necessary.

2a. Local Site Reporting to Lead IRB

To report local events (unanticipated problems, etc.) to the Lead IRB:

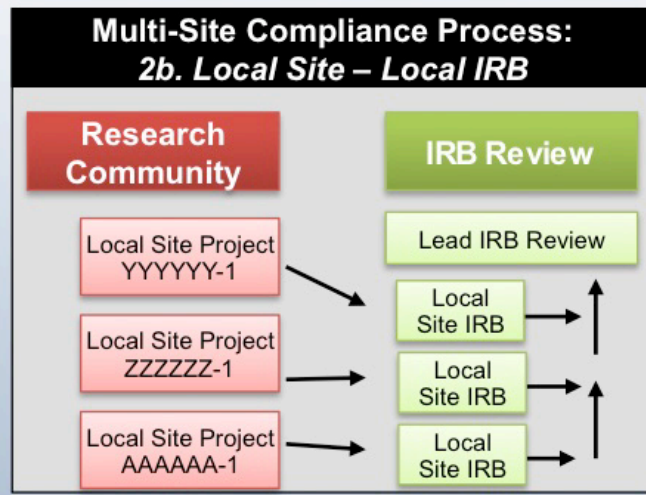
1. Create a new package in your Local Site project.
2. Attach the relevant documentation.
3. Submit this package to the Lead IRB. If required, submit this package to your Local IRB as instructed.



2b. Local Site Reporting to Local IRB only

To report local events only to the Local IRB, it is necessary to do the following:

1. Create a new package in your Local Site project.
2. Attach the relevant documentation.
3. Submit this package to your Local IRB.



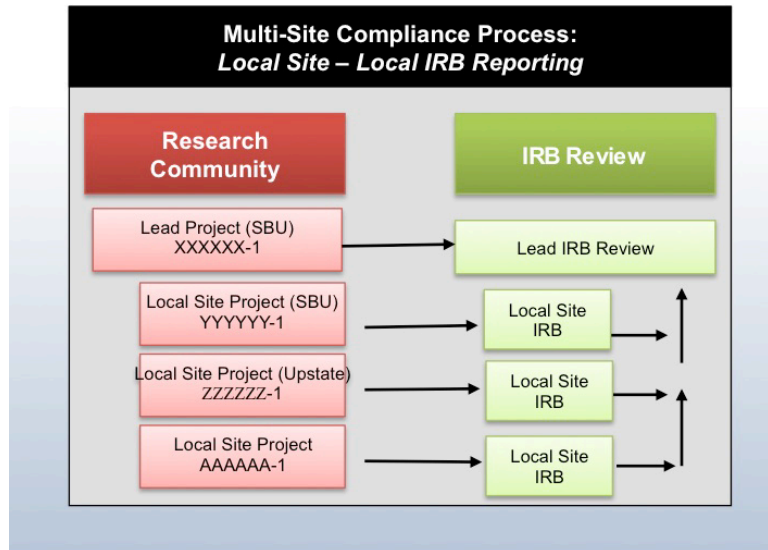
Continuing Review Submissions

Submit to your local IRB office with complete documentation.

Local Site Reporting to Local IRB

To report local events to the Local IRB:

1. Create a new package in your Local Site project.
2. Attach the relevant documentation.
3. Submit this package to your Local IRB. They will review and provide process to the IRB of record.



Ongoing Submissions (not continuing review)

Submit directly to the IRB of record.

Local Site Reporting to Lead IRB

To report local events to the Lead IRB:

1. Create a new package in your Local Site project.
2. Attach the relevant documentation.
3. Submit this package to the Lead IRB. (If required by local SOP, also submit this package to your Local IRB for their reference.)

