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.
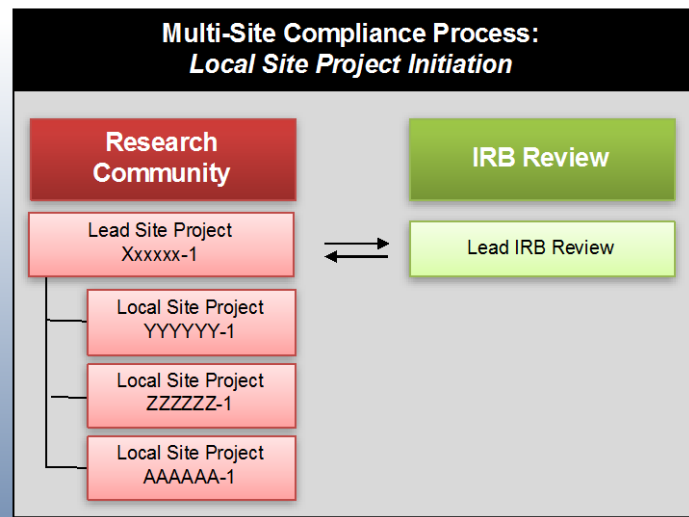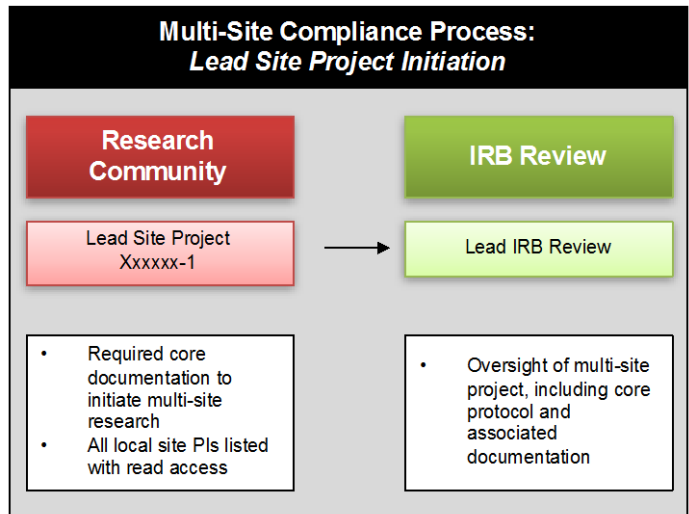
Local Site

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

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

From the Share Project page, select Multi-site.

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 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.

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.

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.

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.

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.

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.

Ongoing Reporting to Boards

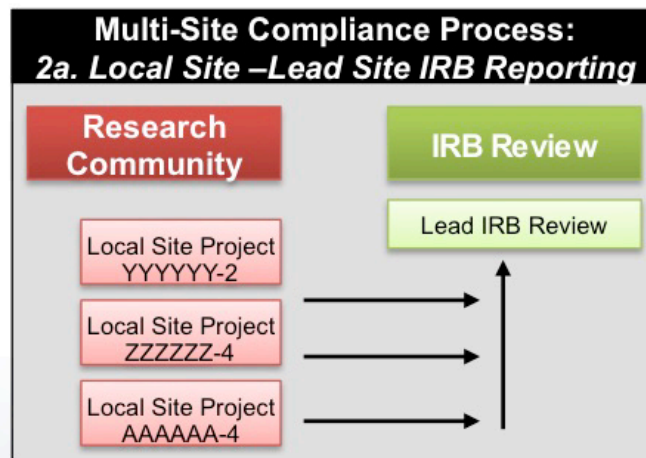Update Lead Site core documentation and report events to Lead or Local IRBs via subsequent packages.

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

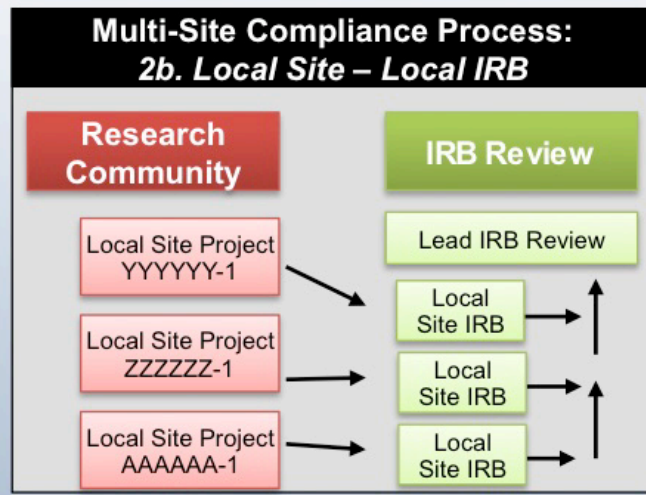To report local events (unanticipated problems, etc.) to the Lead IRB:

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.

Multi-Site Compliance Process:
2a. Local Site –Lead Site IRB Reporting

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.

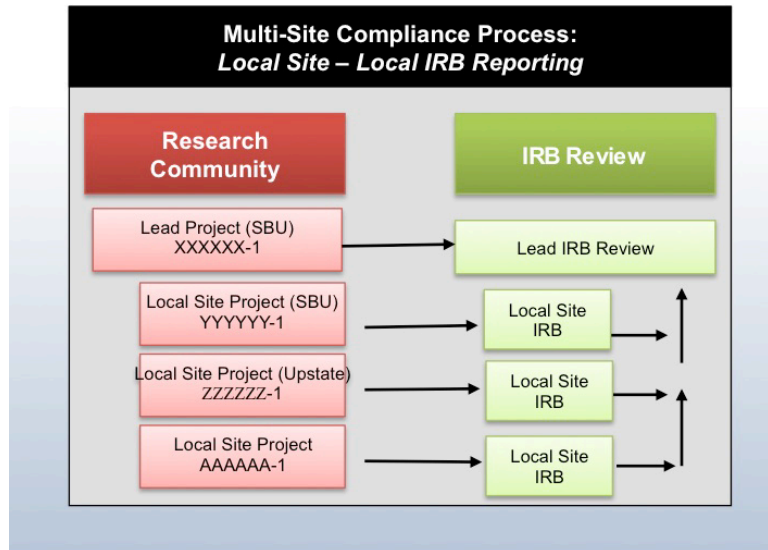3. Submit this package to your Local IRB.

Multi-Site Compliance Process:
2b. Local Site – 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.)