

## Relying on an External IRB: FAQs for Research Teams

The purpose of this document is to provide helpful hints for study teams whose institutions have agreed to rely on an external IRB.

### ***What does relying on an external IRB mean?***

Institutions may agree to use an IRB outside their institution to oversee a research study or studies. This is called ceding or deferring IRB review.

### ***How do I know whether a study can be ceded to an external IRB?***

Please contact your institution's [SMART IRB point of contact \(POC\)](#), or check with the office at your site responsible for making determinations regarding whether IRB review will be ceded to an external IRB (usually the IRB office), to find out:

- what research qualifies for ceded review
- how to make requests for ceding IRB review, and
- what, if any, agreement may be in place to cover the specific IRB review arrangement.

### ***Does my institution need to sign an agreement in order to rely on an external IRB?***

Generally, a written agreement between the institutions must be executed for an institution to rely on an external IRB. The agreement spells out the responsibilities of the institution providing IRB review as well as the institution relying on the external IRB.

### ***What is the SMART IRB Agreement?***

The SMART IRB Agreement is a national master agreement that allows institutions to avoid having to negotiate individual agreement per study or group of studies. More information about SMART IRB is at <https://smartirb.org> and a list of institutions that have joined SMART IRB by signing onto the agreement is at <https://smartirb.org/participating-institutions/>.

### ***Do I need to obtain sign-off from my home institution, such as from its IRB office, to use an external IRB?***

Generally, yes. Because institutions need to identify the research that falls under their purview, even if an IRB outside the institution oversees some or all of its research, they usually require researchers at least to alert appropriate institutional officials about a study they wish to have reviewed by an external IRB. Institutions often require institutional sign-off before the study can be reviewed by an external IRB. The mechanism by which this “registration” occurs varies by institution. Some, for example, require researchers to provide a brief application in the local electronic submission system. Study teams should check to find out what their institutional requirements are in regard to the use of an external IRB.

### ***What is the role of my local institution, such as my local IRB office, if research is ceded to an external IRB?***

Most reliance agreements, such as the SMART IRB Agreement, require institutions to communicate “local context” issues to the Reviewing IRB. Local context issues can include institutional requirements for informed consent language (e.g., compensation for injury language), attesting to the adequacy of research team training, qualifications and resources available to them to conduct the study, and providing any relevant conflict of interest management plans ( or, in the case of federal agencies, assurances that the participation of their research personnel is permissible and consistent with federal law). The local IRB office is often, but not always, responsible for handling such communications.

### ***How do I request that my institution cede review for my study to an external IRB?***

The mechanism by which this is accomplished varies by institution and by the agreement under which IRB review will be ceded. For example, some institutions use the SMART IRB Online Reliance System (<https://smartirb.org/reliance/>) to have study teams request reliance arrangements, while others require alternate processes.

Many institutions expect study teams to provide a protocol, template consent form, and list of sites and personnel engaged in the study for the institution to determine whether the study qualifies for single IRB review or to decide which institution should serve as the Reviewing IRB. Please contact your institution’s [SMART IRB point of contact \(POC\)](#), or check with the office at your site responsible for making determinations regarding whether IRB review will be ceded to an external IRB (usually the IRB office), to find out more about the processes and procedures required for using that IRB.

### ***How do I submit my documents to the external IRB for review?***

You will need to find out the arrangements in place for submitting to and communicating with the designated Reviewing IRB.

- In some cases, a lead study team, coordinating center, or sponsor will submit documents to the IRB and provide you with documentation of that IRB’s approval for your site.
- Some institutions do not allow sponsors to submit applications to the IRB on the behalf of the study team.
- In other cases, the study team is directly responsible for submitting documents to Reviewing IRB.

### ***How do I know when I can start the research at my site if an external IRB is reviewing the study?***

Obtaining IRB approval is one of often many approvals or sign-offs that study teams must have in place to activate a study. The same institutional requirements must be met for study activation when using an external IRB. Examples include reviews and approvals by other institutional committees (e.g., biosafety, radiation safety, pharmacy, conflict of interest, billing compliance) and executing any clinical trials agreements.

You will need to ensure you have documentation that:

- your site has ceded review to the external IRB; and
- the external IRB approval for the study covers your site.

If the external IRB has approved the study before your site is ready to join, your site will need to be specifically reviewed and approved as a new site, which is usually accomplished via an amendment to the existing study. Activities involving human subjects at your site cannot occur until the external IRB specifically approves your site’s participation in the research and you have obtained all required institutional sign-offs and/or approvals.

## ***What are my obligations when an external IRB is responsible for reviewing my research study?***

The responsibilities of the research team remain largely the same, and include:

- Obtaining sign off from your institution to use an external IRB
- Obtaining initial approval as a participating study site
- Communicating information about study progress to the Reviewing IRB via the mechanism established for such communications (e.g., either to the IRB directly, or to the lead study team or coordinating center)
- Tracking personnel updates, ensuring personnel are qualified and appropriately trained to perform their roles, and providing information about relevant personnel changes to the Reviewing IRB (including confirming personnel are qualified and appropriately trained) to the Reviewing IRB when required and via the mechanism established for such communications (e.g., either to the IRB directly, or to the lead study team or coordinating center)
- Reporting unanticipated problems, noncompliance, and significant new information to the Reviewing IRB via the mechanism established for such communications
- Complying with the Reviewing IRB's policies (e.g., reporting noncompliance, unanticipated problems, and subject complaints)
- Complying with the determinations of the Reviewing IRB
- Using the most current IRB-approved documents, including the protocol, consent forms, and recruitment documents
- Complying with applicable policies from the local institution (e.g., conflict of interest, training and education, research subject compensation processes, billing compliance)
- Working with the lead investigator to make any local updates to the protocol or other approved documents (e.g., consent form or recruitment materials), and ensuring the Reviewing IRB approves these changes before they are implemented
- Communicating applicable study updates with other relevant local institution committees and/or offices (e.g., research billing, radiation safety committees, pharmacy, oncology review committees)