



# Online Reliance System FAQs

## **When should the Online Reliance System be used?**

The Online Reliance System may be used to document use of the SMART IRB Agreement for a specific study. The System will facilitate the process of identifying and documenting a Reviewing IRB and the Relying Institutions, and provide the opportunity to communicate any local context requirements or other concerns. An investigator (or his or her designee) may submit a request for reliance prior to submitting a protocol for IRB review; each reliance request must include a PDF of the study protocol.

## **Who can use the Online Reliance System?**

All [Participating Institutions](#) and their investigators can use the Online Reliance System. See below for help obtaining access to the System. Institutions that have not signed onto the Agreement can contact us at [help@smartirb.org](mailto:help@smartirb.org) for help joining SMART IRB and obtaining access to the Online Reliance System.

## **Do I have to use the Online Reliance System?**

The SMART IRB Agreement does not require Participating Institutions to use the Online Reliance System to determine reliance arrangements. However, Participating Institutions are encouraged to use this System, since it provides a streamlined platform for enabling reliance decisions across multiple institutions. In addition, institutions that use the Online Reliance System during the beta period will have an opportunity to influence the future development of the System over the coming months.

## **Can I integrate the information from the Online Reliance System with my local IRB application?**

UPDATED

The System allows you to download a PDF of the Reliance Request form and the Determination Letter from the original request. These documents can be uploaded to your local applications as determined by each institution.

At this time, The System does not support the ability to download a PDF of an Amendment or of an Amendment Determination Letter. (See below for details about the amendment process).

## **Do reliance arrangements that were made using the SMART IRB Agreement prior to the launch of the Online Reliance System need to be added to the System now that it is live?**

Studies for which reliance determinations have already been made under the SMART IRB Agreement do not need to be entered into the Online Reliance System. While institutions may decide to “re-process” such reliance arrangements in order to have all SMART IRB studies documented in one place, the request would have to go through the workflow with each institution recording their decision in the System; determination dates (i.e., the date of reliance determination) cannot be backdated, and so would reflect an “after-the-fact” arrangement.

## Can I use the Online Reliance System for reliance determinations with institutions that are not participating in SMART IRB?

No; the Online Reliance System may only be used to document reliance arrangements among SMART IRB Participating Institutions that have also registered with the SMART IRB Online Reliance System.

## How can I create an account?

### ***For Institutions:***

Once an institution has joined SMART IRB, the institution must designate and register a Reliance Point of Contact (POC). The SMART IRB [POC](#) listed in your Joinder Agreement will automatically receive an invitation to register as the Reliance POC; however, this role can be delegated by contacting [help@smartirb.org](mailto:help@smartirb.org).

Note: the Reliance POC account is separate from the Joinder account used to join SMART IRB.

### **What does the Reliance POC do?**

The Reliance POC reviews requests for reliance involving their institution and determines whether their organization will be the Reviewing IRB or Relying Institution, as applicable. For requests where the Principal Investigator is from their institution, the Reliance POC will first determine whether the request is eligible for reliance.

### ***For Investigators:***

It is not unusual for an investigator to delegate the responsibility for completing reliance requests — see “submitter” below. To request an account, complete the “[Request Investigator Access](#)” form and follow the instructions. Your request will be forwarded to the Reliance POC for your institution, who must authorize you for access to the system, and this may take a few days. If you have problems registering for your account, please [contact us](#).

### **What does the Submitter do?**

An investigator or “submitter” account will allow you to create, submit, and track reliance requests for your studies. As an investigator, you can delegate this role to a member of your research team (e.g., a study coordinator) by having them request an account. In the initial beta period, only the submitter will be able to login and access a request. However, the Overall PI and Site Investigator(s) will be notified by email about the status of any request submitted on their behalf.

## Can other members of the institution view and act on a reliance request?

In this initial beta phase, each institution can designate a single Reliance POC who will review and make determinations for requests involving that institution. We expect to add capability for an institution to grant additional staff members access to view and act on requests.

Institutions may provide submitter access to any investigators or staff members from their institution who wish to submit a request for IRB reliance; only one request need be submitted for each study. At this time, for each request, a single submitter is able to complete, submit, and view the details in the Online Reliance System.

In future, other kinds of institutional access may be provided and suggestions from users during the beta phase are encouraged.

### **Can the Reliance Point of Contact create and submit a reliance request?**

The Online Reliance System is investigator-driven in an effort to accommodate the wide range of institutions, with varying research portfolios and research infrastructure, that will be using the system. As such, only investigators or a member of their research team can submit reliance requests through the system. Having said that, if an institution's practice is to complete reliance requests on behalf of the investigator, it is possible for the Reliance POC or designee to generate an investigator-level user account for that purpose, using a separate email address from the one used by the Reliance POC account. It is up to the Reliance POC for that institution to determine whether it is appropriate to authorize such an exception at their institution.

### **What information does the submitter need provide in the reliance request?**

- Basic information about the research (title of study, a brief description)
- The Overall Principal Investigator's name and contact information
- The institution that you would like to serve as the Reviewing IRB
- Funding sources (optional)
- Sites that will be engaged in human subjects research for the study, including:
  - The Site Investigator's name and contact information
  - Research activities and targeted subject populations
  - Research personnel names and contact information (optional)
- Supporting documents (PDFs only):
  - Research protocol (required)
  - Consent templates (optional)
  - Other documentation (optional)

The submitter will need to collect information from the engaged sites to include in the request form.

### **What happens if a submitter incorrectly enters an email address or other information?**

Once the request is submitted, the Reliance POC for the Overall PI's home institution is notified to review the request to confirm eligibility. If an error is identified during this initial review for eligibility, the submitter or the Reliance POC for the Overall PI's home institution can reopen the request to make the necessary corrections, including to the email address.

### **How is the Reviewing IRB identified? Can the PI help decide which institution will be the Reviewing IRB?**

When submitting a request for reliance, the investigator or designee identifies a requested Reviewing IRB in the request form. The Overall PI's home institution is given the first option to serve as the Reviewing IRB. If the Overall PI's home institution declines or is unable to serve as the Reviewing IRB, that institution's Reliance POC has the responsibility to propose a Reviewing IRB in the System, and may take the investigator's request into consideration in doing so. Investigators with questions about which IRB is the most appropriate Reviewing IRB for their study are encouraged to contact their SMART IRB POC for assistance before submitting a reliance request in the system.

### **How does a site indicate it will rely on the proposed Reviewing IRB?**

Once a request has been deemed eligible for reliance and a proposed Reviewing IRB has been identified, the Reliance POC for each engaged site will complete a form indicating the site's willingness to rely upon the proposed Reviewing IRB for oversight of that study. Prior to completing this form and as needed, the POC may discuss any outstanding questions or concerns with the Reliance POC for the proposed Reviewing IRB. The proposed Reviewing IRB will review all provided information and decide whether they can take on oversight for each site that has indicated willingness to rely upon the proposed Reviewing IRB. Then they will issue the determination, notifying all parties.

### **Can sites that choose not to rely on the Reviewing IRB still participate in the study?**

Yes, unless use of single IRB review is a sponsor requirement. For sites that choose not to rely on the reviewing IRB, their own IRB can review and approve the study in accordance with their usual procedures.

### **Can sites be added to a request at a later date? UPDATED**

Yes, additional sites may be added to any request that has already resulted in a reliance arrangement. The submitter of the original request (e.g., the overall PI or other study team member) may request to add additional sites. Amendments are submitted and reviewed on a site-by-site basis; only one amendment may be under consideration at a time.

The submitter will need to collect the following information from the new site to include on the amendment form:

- The Site Investigator's name and contact information (required)
- Research activities and targeted subject populations at the new site (required)
- Research protocol for the new site (optional)

### **How do sites communicate whether the SMART IRB or Reviewing IRB's policies and procedures will be used?**

This information should be communicated in the decision-making process. The Reviewing IRB should document and distribute this information when a determination is issued or in a following communication.

### **How is HIPAA privacy review addressed in the reliance determination process?**

When reviewing the reliance request and study materials, each institution should determine whether it will cede HIPAA privacy board review and, if so, confirm that the Reviewing IRB is willing to serve as the privacy board. This communication can occur outside the Online Reliance System and/or when the institution records its willingness to rely on the proposed Reviewing IRB in the System.

### **How is local context information communicated to the Reviewing IRB?**

The System allows engaged sites to communicate local context considerations to the proposed reviewing IRB as they express their willingness to rely for a given study.

### **Is there any plan to record local context in an institution profile so that this information is readily available in the Online Reliance System?**

Discussions among the SMART IRB working groups are underway to determine how best to capture institutional information and harmonize this information with profiles used by other entities (e.g., NCI CIRB).

## What are next steps for a study after a reliance determination has been reached in the system?

UPDATED

After a reliance determination has been reached, the Reviewing IRB begins the IRB review process using its own processes. Only the initial reliance determination is made within the Online Reliance System.

In addition, the submitter of the original request will be able to add additional engaged sites to the request.

## Who can submit an amendment to add a new site to a request? NEW

At this time, only the submitter of the original request will be allowed to add additional sites to the study through the amendment process.

## When can I submit an amendment to add a new site(s) to my request? NEW

Once a reliance determination has been reached for your request, the Summary page will contain an Amendments section and an “Add a Site” button.

Note: requests that are under review cannot be amended until a reliance determination is issued. To revise a request that has closed with no reliance determination, please submit a new request.

## How do I (as the Submitter of a request) submit an amendment to add a new site to my request? NEW

Once a reliance determination has been reached, the Summary page for the request will contain an Amendments section and an “Add a Site” button. Click the “Add a Site” button to begin.

The screenshot shows the SMART IRB Reliance system interface. At the top, there is a navigation bar with 'Home', 'New Request', and 'Logout' options, and a user login status: 'You are logged in as applicant@ridgeview.net'. The main content area is titled 'Request Details' and features a sidebar on the left with a 'Demo' label. The sidebar contains a list of navigation items: 'Summary', 'Reliance Request', 'Reliance Pre-Check', 'Reviewing IRB', 'Involved Institutions', and 'Determination', each with a green dot indicating completion. The main content area is divided into several sections: 'Principal Investigator (PI)' (Sophia Channing, Ridgeview Research Facility), 'Requested Reviewing IRB' (Ridgeview Research Facility), 'NCT Number' (Add NCT Number), and 'Protocol Number(s)'. The 'Summary' section is highlighted with a red box and contains the following information: 'Overall Status: Reliance Reached', 'Finalized Reliance Determination(s)', and a list of actions: 'The Reviewing IRB will notify the Overall PI of its decision, any required modifications, and the date by which renewal of approval is required.', 'View the Determination Letter for more information. Find Amendment Determinations in the Amendment section.', 'This decision applies only to the determination of IRB reliance, and does not reflect IRB approval of the research project itself. Approval for each relying site must be obtained from the Reviewing IRB prior to initiating study activity at each site.', and 'You have the option to add additional sites through an amendment process.' Below the summary, there are two sections: 'Relying' (listing Ridgeview Research Facility and Oxlane Institute of Technology) and 'Not Relying' (stating there are no sites that are not relying). The 'Amendments' section is highlighted with a red box and contains the text 'No amendments have been created for this request.' and an 'Add a Site' button. A red arrow points to the 'Add a Site' button with the text 'Click to add a new site'.

### What information will I need to provide to add a new site to my request? **NEW**

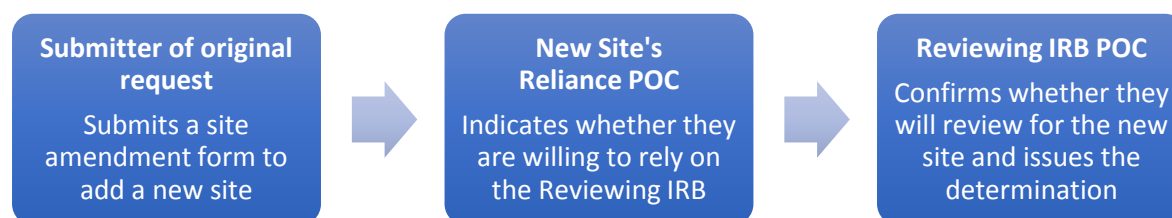
The submitter of the original request will need to obtain and provide the following information on the site amendment form:

- The Site Investigator's name and contact information (required)
- Research activities and targeted subject populations (required)
- Research protocol for the new site (optional)

### Can I add more than one site to my request? **NEW**

Yes; however only one amendment can be under consideration at a time. The submitter must wait until an amendment reaches a determination before attempting to add an additional site.

### How does the amendment process work? **NEW**



After the submitter completes and submits the site amendment form, the system notifies the Reliance Point of Contact (POC) for the new site, who is provided access to the request. The POC for the new site is asked to review the amendment form, the original reliance request, and related supporting documentation, and to discuss any issues with the Reviewing IRB POC. The new site's POC will then indicate their site's willingness to rely upon the Reviewing IRB for oversight of the research.

The Reviewing IRB POC will review the information for the new site and, if the site has indicated it would like to rely upon the Reviewing IRB, decide whether the Reviewing IRB will take on oversight of the research for this site. The Reviewing IRB POC will then issue a determination specific to the new site.

Parties involved in the amendment process will be notified at the appropriate points in time in the amendment process and provided with instructions for any actions that may be required.

### Which sites can I add to my study through the amendment process? **NEW**

The amendment process may be used to: (1) to request to add a new site to an existing reliance arrangement, or (2) request that a nonrelying site from the original request be reconsidered for reliance.

The submitter will be able to add any [Participating Institution](#) to the request through the amendment process, with the following exceptions:

- A site that was included in the original request and is already listed as a Relying Institution for that request.
- A site that is an independent IRB organization and therefore cannot be a site engaged in research.

**Why can't I download the Amendment form or Determination Letter for the amendment? NEW**

For the initial release of the Add a Site Amendment feature, the Amendment form and Amendment Determination Letter will only be available through the Online Reliance System. We are working to create a downloadable version of the Add a Site Amendment form and Amendment Determination Letter. We hope to have these features available shortly. In the meantime, we suggest printing the Amendment form and Amendment Determination Letter to PDF.