

IREx is a tool coordinating centers and lead study teams (also known as “Study Managers”) can use to centrally capture all the reliance documentation needed from participating sites to help support the single IRB (sIRB) and the sIRB process.

IREx OFFERS RESOURCES TO SUPPORT THE STUDY MANAGER & SINGLE IRB PROCESS



DELEGATING TASKS TO THE STUDY MANAGER

The additional effort required to support sIRB review requires collaboration between the sIRB and Study Managers. Delegating the tasks as outlined below allows the sIRB to focus on the IRB review and human research protections while the Study Manager focuses on site communications and coordination.

SINGLE IRB TASKS

- Create study in IREx
- Upload initial approvals for the lead site or overall study

STUDY MANAGER TASKS

[see detailed descriptions below]

- Manage site access to study in IREx
- Track site readiness for sIRB review
- Download sites' local considerations for submission to the sIRB
- Upload site and ongoing study approvals

MANAGE SITE ACCESS TO STUDY IN IREX



IREx Study Managers use IREx to manage sites' access to their study and notify sites of their access. Study Managers can add and remove sites at any time, using the site name or Federalwide Assurance (FWA) number. Additionally, IREx provides template reliance instructions (to be approved by the sIRB) that may be helpful in explaining how to use IREx to rely on the sIRB.

TRACK SITE READINESS FOR SIRB REVIEW



IREx Study Managers can monitor each site's progress completing the reliance documentation, including whether sites have (a) executed the reliance-related agreements, (b) documented a cede decision, and (c) provided study-specific local considerations. Study Managers also have a Dashboard where they can track the progress of multiple studies at a glance.

DOWNLOAD SITE'S LOCAL CONSIDERATIONS FOR SUBMISSION TO THE SIRB



As sites begin the reliance process and document the required information, IREx Study Managers receive automated notifications of site progress. Once a site has completed all documentation, the Study Manager is automatically notified and can download the information and submit it to the sIRB for review.

UPLOAD SITE AND ONGOING STUDY APPROVALS



Once a site has sIRB approval, the IREx Study Manager adds the site's approval documents and review dates to IREx, which automatically notifies the site's HRPP and study team of approval. The IREx Study Manager can also upload continuing reviews, study-wide amendments and site-specific amendments.