Introducing the New Single IRB Application

January 2019

Overview

- What is the sIRB application?
- Completing the initial sIRB application
- Adding study sites
- Making changes to the overarching study and study sites
- Tips and resources

Disclaimers

- For now, sIRB application is for studies involving 4 or more sites for which the UW will be reviewing IRB
- sIRB application is a new process, with a learning curve for everyone
- Before starting a sIRB application, study teams are encouraged to reach out to the HS IRBs Reliance Team (irbreliance@wisc.edu) to discuss this process in more detail

What is the sIRB Application?

And why do we have it?

sIRB Application Basics

- A separate application in ARROW for studies that:
  - Involve 4 or more sites and
  - UW will serve as the reviewing IRB
- Application requires a standalone protocol
  - sIRB application is much shorter than regular one because protocol will cover many things normally asked in the application
- Only for studies undergoing full (convened) IRB or expedited review
  - NIH sIRB policy and regulatory sIRB requirement do not apply to exempt research

Why a separate application for sIRB?

- sIRB mandates from NIH and revised regulations
  - NIH in effect already
  - January 2020 for regulatory changes
- Current application format and workspaces do not easily accommodate larger scale studies
- Need better ways to collect and store information about relying sites
  - Local context information
  - Site-specific recruitment and/or consent documents

How Does the IRB Review Process Work?

- Overall study protocol and UW-Madison activities approved first via usual process
  - Including template and UW-Madison study documents
- Sites listed in the overall study protocol/application are added and approved separately via expedited changes
  - Including site-specific study documents, such as consents and recruitment materials
- This approach provides study teams with maximal flexibility to add sites when they are ready
  - More than one site can be added at a time!

Completing the Initial sIRB Application

What You Need to Get Started

Listing Sites and External Personnel

- Study sites relying on the UW will be listed in the study location section
  - List any site reasonably likely to be involved in the study
- Delegation logs listing external personnel will NOT be uploaded in the overall application
  - Uploaded to add a site form later
- Other details about each site will be addressed later when each site is added to the study

What Documents to Upload and Where

- sIRB application includes uploads for template documents, including consent forms and recruitment materials
  - Templates = fairly generic versions of study documents that can be adapted for use with each study site
  - No template needed for authorization forms, if needed
- UW-Madison documents will be uploaded in the application per usual
- Site-specific documents will be uploaded in the add a site form when each site is formally added to the study

Adding Study Sites

Getting Final Approval for Each Site

How Are Sites Approved?

- Sites listed in the overall application only approved in theory with approval of the overall application
- Each site listed in the approved overall application is then formally approved via the add a site process
- While it sounds complicated, this model for approving sites is followed by independent IRBs and is typically the fastest route to approval for study sites
  - Multiple sites can be submitted at the same time!

How to Add a Site

- New "add a site" button in the main study workspace
- Opens a new form with a picklist of "approved" sites
- Pick the site being added and complete the form for that site
- Sites can only be added per add a site form
- Sites not in the picklist need to be added via a change to the overall application

Completing the Add a Site Form

- Upload delegation log for the site
- Address questions about local context for that site, such as any applicable state laws or other local requirements
  - Will require input from the local study team
- Upload site-specific consent and recruitment documents
  - Create these based on approved templates
  - Add a site form will include links to approved templates to make it easier to use
  - Site-specific authorization forms also uploaded here

Making Changes to the Overall Study and Study Sites

Where to Change Things

Changes to the Overall Study

- Same change of protocol process as usual
- Examples of typical changes for sIRB studies
  - Revisions to the overall study protocol, such as changes in procedures or adding a sub-study
  - Updating template study documents
  - Changing funding
- Personnel change form is only for UW-Madison personnel
- As with regular studies, only one change can be submitted at a time for the overall study application

Changes to a Site

- Each site workspace has a change button to allow changes to that site
- Examples of changes to a site:
  - Updated delegation log to reflect personnel changes at that site
  - Revisions to site-specific study documents
  - Changes to conflict of interest plans
- Only one change per site can be submitted, but multiple sites can have changes in progress at the same time

What about Continuing Review and Reportable Events?

- Same continuing review form will cover all sites
  - No site-specific form required
  - Continuing review form has been revised to ask for information about enrollment numbers at each site
- Same reportable event form will cover all sites
  - No site-specific form required
  - Reportable event form has been revised to allow study teams to indicate if an event is study-wide or only affects one or more specific sites

Tips and Resources

I'm Confused, Help!

Tips

- Consult with the Reliance Team (irbreliance@wisc.edu) early when planning a multisite study and well before submitting a sIRB application
- Develop good channels of communication with study teams at relying sites
  - Their help with providing information about local requirements and developing site-specific study documents is critical
- Do not try to add sites before the relying site study team is ready to move forward
  - Relying study teams should start the cede review process with their own IRB around the same time as the site is added at the UW

Resources

- Single IRB Basics page on the HS IRBs website
  - Continues to be updated with new resources
- Single IRB Guidance for UW Research Administrators
- SMART IRB resources for study teams
- As always, the HS IRBs Reliance Team is happy to assist with any questions (irbreliance@wisc.edu)