



SIRB SITE-CONTROL REVIEW INSTRUCTIONS

As a board reviewer, you may be asked to review an application for a Single IRB (SIRB) study that the site-control model. These instructions are intended to help board members navigate ERICA in order to complete a thorough review of the information for each participating site the University of Utah IRB oversees.

If you have questions about anything relating to the main application or site-controlled applications, please contact your IRB Coordinator.

If you prefer a visual presentation of these instructions, please visit the [Board Member Video Library](#) to find a video demonstration.

CONTINUING REVIEW:

Step 1: Click on the link of the study (either in your board member inbox or the email assignment from ERICA). The main Continuing Review application you are reviewing will remain the same; open the "Printer Version" of this and conduct review as you would any other application.

Step 2: While still in the print view, scroll down to the section called "Progress of Sites and Enrollment," where the list of site-controlled locations is displayed.

Progress of Sites and Enrollment

Select each site to update the enrollment information.

List of Study Controlled Locations

Site Name	Investigator's Name	Enrollments since Last CR	Enrollments as of Today	Non English Speakers	Withdrawn
View Intermountain Primary Children's Hospital	Matthew Szadkowski	494	800	1	0
View Nationwide Children's Hospital	Julie Leonard	1571	2907	44	0

List of Site Controlled Locations

Site Name	Investigator's Name	Enrollments since Last CR	Enrollments as of Today	Non English Speakers	Withdrawn
Emory University	Claudia Morris		0	0	0
Cincinnati Children's Hosp Med Ctr	Lauren Riney	459	969	0	0
Children's Hospital Colorado	Kathleen Adelgais	624	1104	70	0
University of New Mexico	Robert Sapien	109	309	1	0
Children's Hospital of Philadelphia	Daniel Corwin		12	0	0

Any participating site listed here should be opened by clicking the name of the site. From there, the participating site specifics and the corresponding documents and attachments may be reviewed.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.



<p>Step 3:</p>	<p>The participating site application should be reviewed as any other application, including opening and reviewing attached documents (such as site-specific consent forms). Repeat this process for reviewing each site, taking notes (as applicable) to add to your main board member checklist. Individual checklists are not necessary for each site.</p>
<p>Step 4:</p>	<p>The IRB Staff should have provided you a summary document that outlines participating site differences/progress/changes as applicable. Please review this document and verify if the information is approvable. You may choose to base your board member checklist summary off this document. In your board member checklist summary, please note any participating site study specifics that are different from the main study. After opening and reviewing all applicable sites, you are now prepared to fully complete your board member checklist.</p>
<p>Step 5:</p>	<p>If reviewing the application at board, please make mention of the fact that this is a study where the University of Utah is acting as the Single IRB, and note any site differences that may need special consideration during your presentation.</p>

AMENDMENT:	
<p>Step 1:</p>	<p>Click on the link of the study (either in your board member inbox or the email assignment from ERICA). The main Amendment application you are reviewing will remain the same; open the “Printer Version” of this and conduct your review as you would any other application, filling out your board member checklist per usual.</p>
<p>Step 2:</p>	<p>While still in the “print view,” you will scroll down to the to Section 5, “Site Controlled Amendments”</p>

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5. Site Controlled Amendments

Study locations that are affected by these changes.

Site Name	Link	Status
Children's Hospital Colorado	Site_00000069_AM_03	In Review
Nationwide Children's Hospital	Site_00000068_AM_03	In Review
University of Pittsburgh Medical Center	Site_00000071_AM_02	In Review
Children's Hospital of Michigan	Site_00000070_AM_03	In Review
Children's Hospital of Philadelphia	Site_00000065_AM_03	In Review
Children's National Medical Center	Site_00000067_AM_04	In Review
University of California San Francisco	Site_00000066_AM_04	In Review

Any participating site that has a "link" should be opened by selecting the individual item. From there, you can review the participating site specifics and the corresponding documents and attachments.

Step 3:	Review the participating site application as you would any other application, including opening and reviewing attached documents (such as site-specific consent forms). Repeat this process for reviewing each site, taking notes (as applicable) to add to your main board member checklist. You do not need to fill out an individual checklist for each site.
Step 4:	The IRB Staff should have provided you a summary document that outlines participating site differences/changes as applicable. Please review this document and verify if the information is approvable. You may choose to base your board member checklist summary off this document. In your board checklist summary, please note any participating site study specifics that are different from the main study. After opening and reviewing all applicable sites, you are now prepared to fully complete your board member checklist.
Step 5:	If you are reviewing the application at board, please make mention of the fact that this is a study where the University of Utah is acting as the Single IRB, and note any site differences that may need special consideration during your presentation.

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