Board Member Guidance Series

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 <u>Board Member Video Library</u> to find a video demonstration.

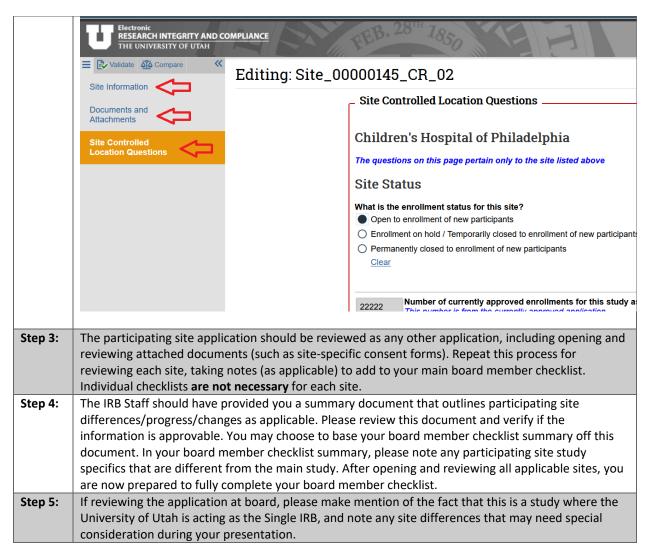
tep 1:	Click on the link of the study (either in your board member inbox or the email assignment from									
	ERICA). The main Continuing Review application you are reviewing will remain the same; open the									
	"Printer Version" of this and conduct review as you would any other application.									
tep 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	Site Name	Investigator's Name	Enrollments since Last CR	Enrollments as of Today	Non English Speakers	Withdrawn				
	Intermountain Primary Children's Hospital	Matthew Szadkowski	494	800	1	0				
	Nationwide Children's Hospital	Julie Leonard	1571	2907	44	0				
	List of Site Controlled Locations									
		Investigator's	Enrollments since	Enrollments as of	Non English	Withdrawn				
	Site Name	Name	Last CR	Today	Speakers	withdrawn				
	Site Name Emory University		Last CR	Today 0		0				
		Name	Last CR 459	•	Speakers					
	Emory University Cincinnati Children's Hosp	Name Claudia Morris Lauren Riney	459	0	Speakers 0	0				
	Emory University Cincinnati Children's Hosp Med Ctr	Name Claudia Morris Lauren Riney	459	0 969	Speakers 0 0	0				

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.



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AMENDN	AMENDMENT:				
Step 1:	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.				
Step 2:	While still in the "print view," you will scroll down to the to Section 5, "Site Controlled Amendments"				

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	5. Site Controlled Amendments						
	Study locations that are affected by these changes.						
	Site Name		Link	Status			
	Children's Hospital Colorado Nationwide Children's Hospital University of Pittsburgh Medical Center Children's Hospital of Michigan Children's Hospital of Philadelphia Children's National Medical Center University of California San Francisco		Site_00000069_AM_03 Site_0000068_AM_03 Site_00000071_AM_02 Site_00000070_AM_03	In Review In Review In Review In Review			
			Site_00000065_AM_03 Site_00000067_AM_04 Site_00000066_AM_04	In Review In Review In Review			
	Any participating site that has a "link" should be opened by selecting the individual in you can review the participating site specifics and the corresponding documents and						
	Editing: Site_00000010_AM_03						
	Documents and Attachments		Site Information				
			The ERICA System has two options for mana, 1. <u>Default Option</u> : ERICA application and E completely controlled by the Responsibl 2. <u>Site Control Option</u> : ERICA application a can be controlled by the Responsible PI Site PI. The UU IRB staff must activate t about this option, visit the IRB website.	ERICA activities for the site are e PI. and ERICA activities for the site , but can also be controlled by the			
			Site Name: University of California Los Angeles (UCLA)	A)			
			Site Principal Investigator Mark if Same as Responsible Investigation	tigator (syncs with			
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						
Step 4:	not need to fill out an individual checklist for each site. 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						
Stop F.	complete your board me		oso maka mantian of the fact t	hat this is a study			
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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