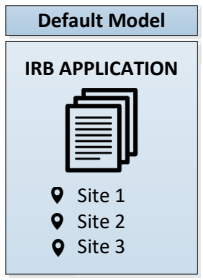
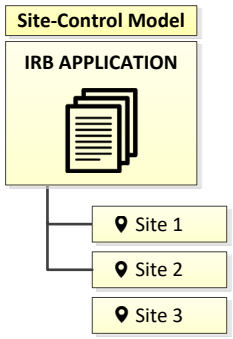
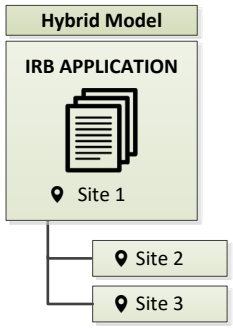
INSTITUTIONAL REVIEW BOARD
THE UNIVERSITY OF UTAH

Single IRB
ERICA MULTI-SITE MANAGEMENT MODELS

The University of Utah IRB has three different models available for managing multi-center research, and there are benefits and challenges related to each model. This guide is designed to assist you in choosing which model work best for your research study and provide information on how to manage submissions within each model.

Work closely with the IRB staff when making your choice. The IRB staff will provide recommendations and make the final determination regarding which model will be activated in ERICA.

Default	Site-Control	Hybrid
		

The ***Default Model*** combines information for all sites within the main IRB application. There is one workspace that contains the full IRB application, site-specific information, and all study documents for all sites. In order for the IRB application to progress through IRB review and approval, all of the sites listed must have completed all reliance requirements and have all site specific documents ready for review.

Benefits:
- This model provides the benefit of having multiple sites and the protocol reviewed and approved within one review process.

Challenges:
- If one or more of the listed sites are not fully prepared for IRB review, the review process is halted until every site is fully prepared for IRB review.
- Sites do not receive automated study notifications, unless they have an ERICA profile and are listed in the application. In this case, sites will receive all notifications, regardless of the relevance or applicability to their site.

The ***Site-Control Model*** separates each participating site into their own IRB site application, which is connected to the main IRB application. Each participating site has their own "workspace" separate from the main IRB application. Each site application goes through their own IRB review and approval process.

Benefits:

- This model allows participating sites to be managed independently from the main IRB application.
- This model provides the benefit of having the main IRB application go through the IRB review and approval process while participating sites are working on completing all reliance and site-specific requirements.
- Each participating site application can be submitted for IRB review and approval when they are ready, and are not beholden to the progress or delays caused by other sites.
- Sites will receive automated study notifications relevant to their site application.

Challenges:

- Sites that have their own participating site application must have a site investigator (SI) listed. The SI must have an ERICA account and profile in order to have access to the application, enter required information, and receive study notifications.

The ***Hybrid Model*** is a combination of the Default and Site-Control Models where one or more participating sites are attached to the main IRB application, while other participating sites are separated into their own site application "workspaces". This model is typically used when the lead site is listed under the main IRB application to be reviewed and approved in conjunction with the main IRB application.

Benefits:

- This model provides the benefits of both the Default and Site-Control Model.

Challenges:

- Determining which sites to keep with the main application and which sites to "peel off" into their own participating site applications can be challenging at the early stages of the review process.
- Once a site has been "peeled off" and given their own participating site application workspace, they cannot be re-integrated into the main application.

External ERICA Access

An individual who is not a faculty member, employee, student, or official representative of the University of Utah will require an external user account for initial and ongoing access to the ERICA system. If possible, these accounts are established in conjunction with the external user's home institution/organization, where the user's identity and credentials are already verified and managed. The RI should work with the IRB to determine who requires an external ERICA account. Further instructions for setting up an external ERICA user account will be provided by the IRB.

ERICA Roles

ERICA utilizes "user roles" to grant different levels of access to applications. Each role allows the user to access, edit, and submit information in the system differently. At a minimum, all applications must include the following personnel:

Responsible Investigator (RI):

- Every IRB application requires one user designated as the "Responsible Investigator" (RI).
- The RI is listed in the main application (similarly to a "principal investigator") and has full rights and access to the complete IRB application ***and*** all participating site-level applications.
- The RI is responsible for the overall conduct of the study and ensuring the ERICA application is complete, accurate, and current at all times.
- The RI signs off on participating site-level application submission after the SI makes submission but has the option of allowing the SI submission without RI sign off.

Site Investigator (SI):

- "Site Investigators" (SI) have rights and access to edit and control ***their*** participating site application, but can only ***view*** the main IRB application.
- The SI can be the same person as the RI.

More details about the other available user roles, as well as their rights and access in ERICA are listed in the tables below.

Main Study-Level Rights & Access					
Role	**View the application & workspace**	**Edit the application**	**Run application activities**	**Submit the application**	**Receive notices**
Responsible Investigator (RI)	X	X	X	X	X
RI Contacts	X	X	X		X
RI Guests	X				
Site Investigator (SI)	X				X
SI Contacts	X				X
SI Key Personnel	X				
SI guests	X				

Participating Site-Level Rights & Access					
Role	**View the application & workspace**	**Edit the application**	**Run application activities**	**Submit the application**	**Receive notices**
Responsible Investigator (RI)	X	X	X	X	X
RI Contacts	X	X	X		X
RI Guests	X				
Site Investigator (SI)	X	X	X	X	X
SI Contacts	X	X	X		X
SI Key Personnel	X				
SI guests	X				

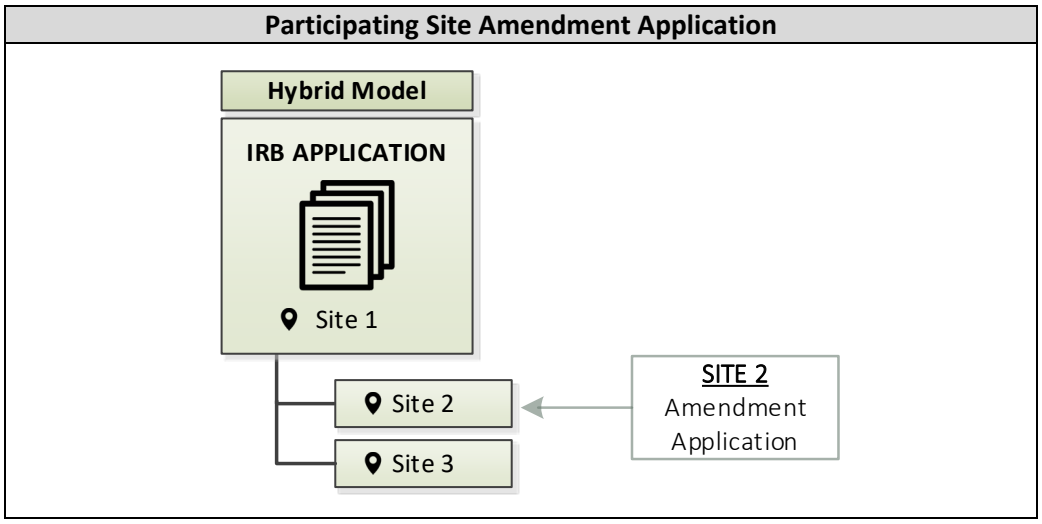
Amendments

The ***Default Model*** amendment application must be submitted to the IRB through the main IRB application in order to make any changes to the IRB application, add a participating site, or make changes to any participating sites.

The ***Site-Control Model***:

Site Application Amendments: amendment applications can be submitted to individual site applications independent from the main IRB application if there are changes that only impact a particular site. The SI can submit an amendment via their participating site application.

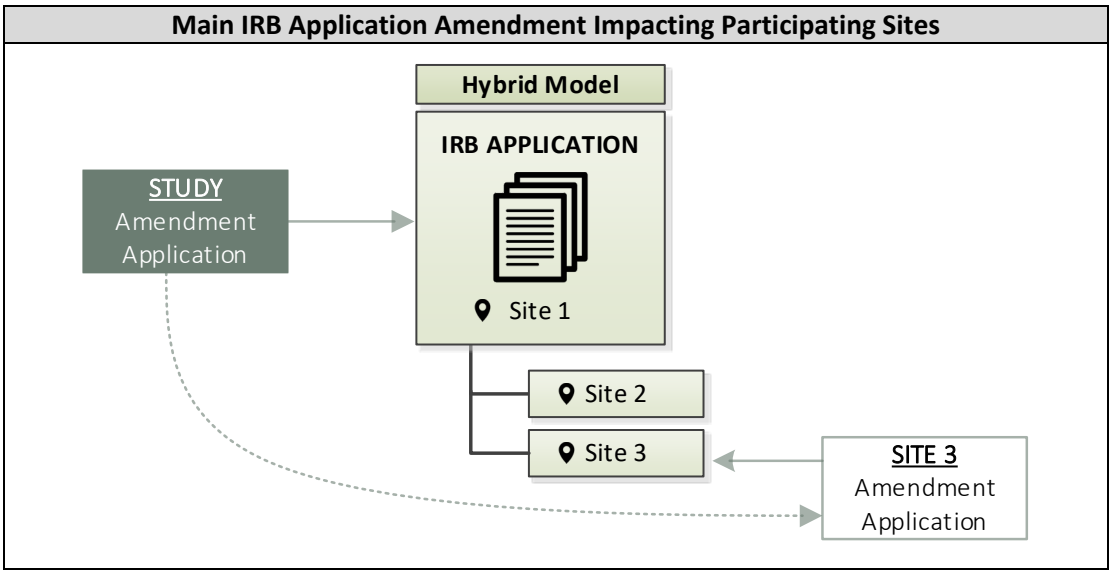
Example: the SI has changes to the local study team and their site specific consent documents need updated contact information. These changes do not impact the overall study protocol or other sites and can be submitted through a participating site page amendment application.



Main IRB Application Amendments: Amendment applications can be submitted by the RI on the main IRB application for any study wide changes and/or protocol changes. Within the amendment application, the RI indicates which, if any, of the participating site applications are impacted by the amendment. By selecting the site applications that are impacted by the study wide amendment, ERICA will automatically create individual site amendments to the participating site applications so the SI can make the corresponding changes to their site application.

Example: The RI submits an amendment to the main IRB application that adds a new study procedure and consequently requires the consent form to be updated with a description of the new procedure and the risks associated with the new procedure. Each individual site will also be required to update their site-specific consent forms. In the amendment application the RI will select that all the participating sites are affected by

this amendment. ERICA will then generate an amendment within each site application so the revised site consent form can be uploaded by each participating site.



Hybrid Model amendments are treated similarly to the Site-Control Model. However, any changes to participating sites that are 'housed' within the main IRB application will require an amendment to the main IRB application.

Report Forms

Report forms in ***all three models*** are submitted by the RI through the main IRB application. SI should work with the RI for submitting a report form for any reportable events that have occurred at their site.

Continuing Reviews

With the ***Default Model*** continuing review (CR) applications are created and submitted by the RI through the main IRB application. The RI will be responsible for retrieving all CR data from participating sites and including them in the CR application.

With the ***Site-Control Model*** continuing review (CR) applications are created and submitted by the RI through the main IRB application. When the CR application is created, a new activity "Go to Continuing Review" activity is created within each participating site application. SIs are able to report their site-specific CR data through this activity on their participating site application. The RI is also able to report participating site CR data through the CR application if they prefer.

With the ***Hybrid Model*** continuing review applications are similar to the Site-Control Model. CR data from sites which are not 'site-controlled' and are listed in the main IRB application will need to be submitted by the RI in the main CR application.