

Click IRB Quick Guide

Comparing Various Submission Types



Key features in the life cycle of various types of Click IRB Submissions have many similarities and a few notable differences. The table highlights some of the exceptional characteristics of each type of submission, including Parent-Child records, as it proceeds through the Click system and is not meant to be a comprehensive summary of changes.

The Click IRB Workflow Cycle

Study State	Initial Study	Modifications	Continuing Review	Reportable New Information
Pre-Submission	<ul style="list-style-type: none"> • Protocol required • HIPAA language in Consent • Basic information collected in SmartForm • Templates in Click Library 	<ul style="list-style-type: none"> • Two types: Study Team Member or Other Parts of the Study • Only one open modification of each type permitted 	<ul style="list-style-type: none"> • Check 4 milestone boxes = Closes Study • Different approach to capturing key information for IRB continuing review 	<ul style="list-style-type: none"> • Special attachment required under certain circumstances • New terminology
Pre-Review	Communications occur in Click system with accompanying notifications to PI/PI Proxy/ Primary Contact	<i>Mirrors initial study workflow</i>	<i>Mirrors initial study workflow</i>	<i>Mirrors initial study workflow</i>
Review	Transparency regarding Committee or Non-Committee review	<i>Mirrors initial study workflow</i>	<i>Mirrors initial study workflow</i>	<i>Mirrors initial study workflow</i>
Post-Review	IRB Determination communicated in Click system and via email notification to PI/PI Proxy/Primary Contact	<i>Mirrors initial study workflow</i>	<i>Mirrors initial study workflow</i>	<i>Mirrors initial study workflow</i>
Review Complete	<ul style="list-style-type: none"> • Approval to start study • “Parent” record 	“Child” record	“Child” record	“Child” record

Submitting Continuing Reviews and New Information

The table below summarizes how to get started submitting each type of information to the IRB.

To submit this type of information...	...start here...	...and click this button	Notes
Continuing review updates for an active study	From the active tab, click the study name (see Accessing a Study on page 11)	Create Modifications/CR	You can submit a continuing review and a modification at the same time. The first prompts you to identify the type of information to submit. To request study closure, submit a CR. Based on the research milestones completed, the study may be closed.
Modifications for an active study			
Request to close study			
New information or an adverse event report	For new information about a particular study, start from the Active tab and click the study name (see Accessing a Study on page 11)	Report New Information	Report new information as soon as you become aware of it. The form identifies the types of information you must report.
	For information affecting multiple studies, start in My Inbox		
New study for review	My Inbox	Create New Study	See Creating a New Study on page 4.
Updates to a new study that hasn't been submitted for IRB review yet	Within the study (see Accessing a Study on page 11)	Edit Study	See Editing a Study on page 6.