



BruinIRB Quick Reference Guide: Update Study Details (01/2024)

Overview

UCLA CTSI/Health Services has requested that the BruinIRB record for all reliance submissions maintain the current protocol and consent versions for the life of the study. UCLA CTSI/Health Services has requested that protocol and consent updates be submitted through BruinIRB to allow for the revised documents to be passed through to the study file in OnCore.

BruinIRB has the capability to modify the application without requiring IRB review. This activity is called **Update Study Details**. This is an administrative function to allow upload of future revisions to the study protocol and consent/assent forms that would normally not require submission to UCLA IRB review. This activity will be limited to FS, PI, and PI proxy(ies).

Non-CTSI/Health Services users are encouraged, but not required, to use the Update Study Details activity to maintain the most current version of study related documents in BruinIRB.

Steps to Completing Update Study Details

Select *Update Study Details*:

Active

IRB-23-5194: Update Study testing

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|---|---|---|--|
| <p>Entered IRB: 10/6/2023 10:44 AM Initial approval: 10/6/2023 Anniversary Date: 10/5/2024 Last updated: 10/6/2023 11:10 AM</p> <p>Next Steps</p> <ul style="list-style-type: none"> <li style="background-color: #4a6984; color: white; padding: 5px; margin-bottom: 5px; text-align: center;">View Site <li style="background-color: #4a6984; color: white; padding: 5px; margin-bottom: 5px; text-align: center;">Printer Version <li style="background-color: #4a6984; color: white; padding: 5px; margin-bottom: 5px; text-align: center;">Create Site Modification <li style="background-color: #4a6984; color: white; padding: 5px; margin-bottom: 5px; text-align: center;">Update Study Details <li style="background-color: #4a6984; color: white; padding: 5px; text-align: center;">Create Post-Approval Report | <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; vertical-align: top;"> <p>Principal investigator: IRBTEST PL_1</p> <p>Lead principal investigator:</p> <p>Submission type: IRB Site</p> <p>Study type: Reliance</p> <p>Primary contact: IRBTEST PL_1</p> <p>PI proxies:</p> <p>PI proxies (Lead site):</p> <p>PI Assurances Completed: Yes</p> <p>External IRB: Advarra (formerly Schulman, Chesapeake, and Quorum)</p> </td> <td style="width: 50%; vertical-align: top;"> <p>IRB office: IRB</p> <p>IRB owner: IRBTEST COORDINATOR_1</p> <p>Letter: Correspondence_for_IRB-23-5194.pdf(0.01) ...</p> <p>Review type: Expedited</p> <p>External study ID: 123456</p> </td> </tr> </table> <div style="margin-top: 20px;"> <pre> graph LR A([Pre-Submission]) --> B([Pre-Review]) B --> C([Pending sIRB Review]) C --> D([Post-Review]) D --> E([Review Complete]) D -- "Modifications Required" --> B C -- "Clarification Requested" --> B </pre> </div> | <p>Principal investigator: IRBTEST PL_1</p> <p>Lead principal investigator:</p> <p>Submission type: IRB Site</p> <p>Study type: Reliance</p> <p>Primary contact: IRBTEST PL_1</p> <p>PI proxies:</p> <p>PI proxies (Lead site):</p> <p>PI Assurances Completed: Yes</p> <p>External IRB: Advarra (formerly Schulman, Chesapeake, and Quorum)</p> | <p>IRB office: IRB</p> <p>IRB owner: IRBTEST COORDINATOR_1</p> <p>Letter: Correspondence_for_IRB-23-5194.pdf(0.01) ...</p> <p>Review type: Expedited</p> <p>External study ID: 123456</p> |
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Complete the amendment cover page, sample language included below:

BruinIRB UCLA Research Administration **TEST** Hello, IRBTEST_PL1

You Are Here: AM GAP 1 > IRBSubmission

Creating New: IRB Submission

Go to forms menu Help

Study Update Information

- * Summarize the updates:**
Reviewing IRB approved Protocol Version 2.0 (version date) with corresponding updates to previously approved consent.
- * Indicate which update type this is:**
 - Protocol Change (no matter how minor)
 - Informed Consent/Assent Form Change

Exit Save Continue

Upload the revised protocol.

BruinIRB UCLA Research Administration **TEST** Hello, IRBTEST_PL1

You Are Here: AM GAP 1

Editing: DRAFT_IRB-24-0008

Go to forms menu Print Help

Basic Study Information

- Attach the protocol:**
 - + Add

| Document | Category | Date Modified | Document History |
|----------|----------------------|---------------|-------------------|
| Update | Blank Doc.docx(0.01) | IRB Protocol | 1/22/2024 History |

Exit Save Continue

Upload any revised consent document:

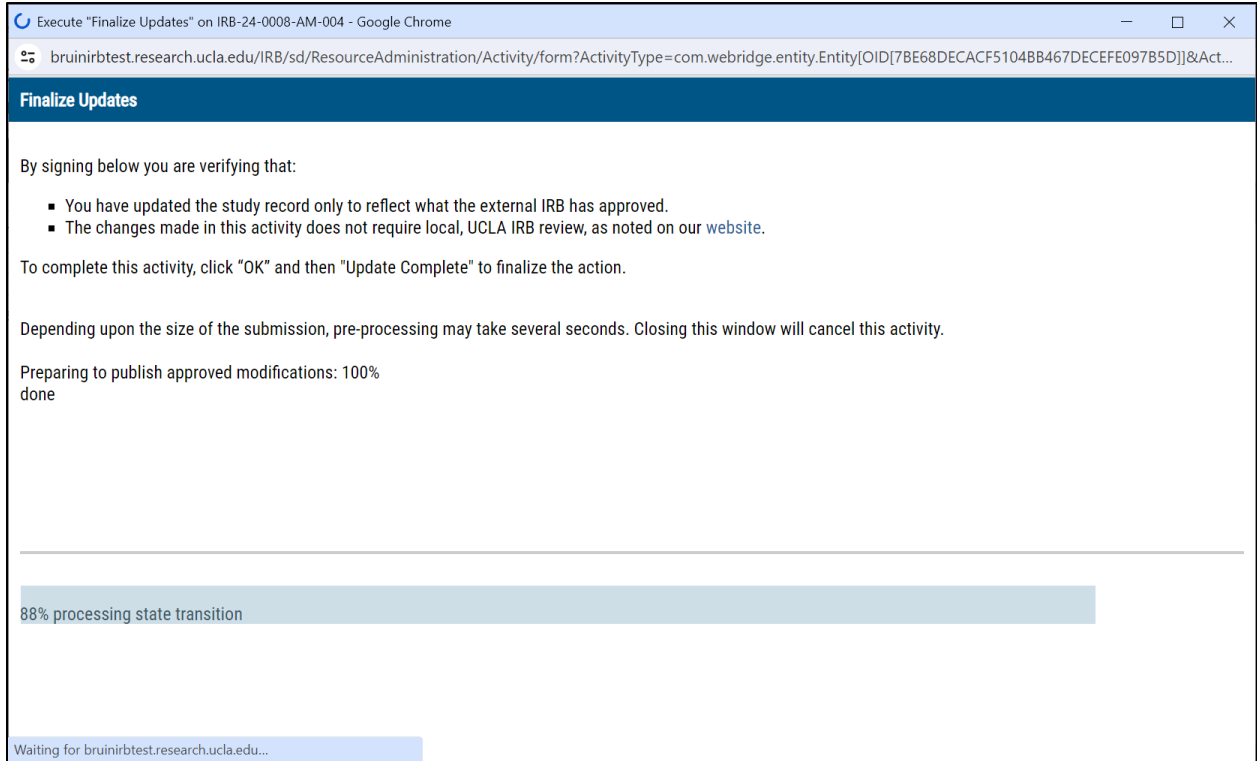
The screenshot shows the BruinIRB web application interface. The browser address bar indicates the URL: bruinirbtest.research.ucla.edu/IRB/app/portal/smartform/edit?Project=com.webridge.entity.Entity%5B70ED2727AFDC11EE28A898FF353A.... The page header includes the BruinIRB logo, UCLA Research Administration, and a 'TEST' badge. The user is logged in as 'Hello, IRBTEST_PL_1'. The main content area is titled 'Local Site Documents' and shows a list of documents. The first document is 'Blank Doc.docx(0.01)' with a category of 'Consent Form' and a date modified of '1/22/2024'. The 'Finish' button is highlighted in dark blue.

Select *FINISH*. You will be directed back to the main study page.

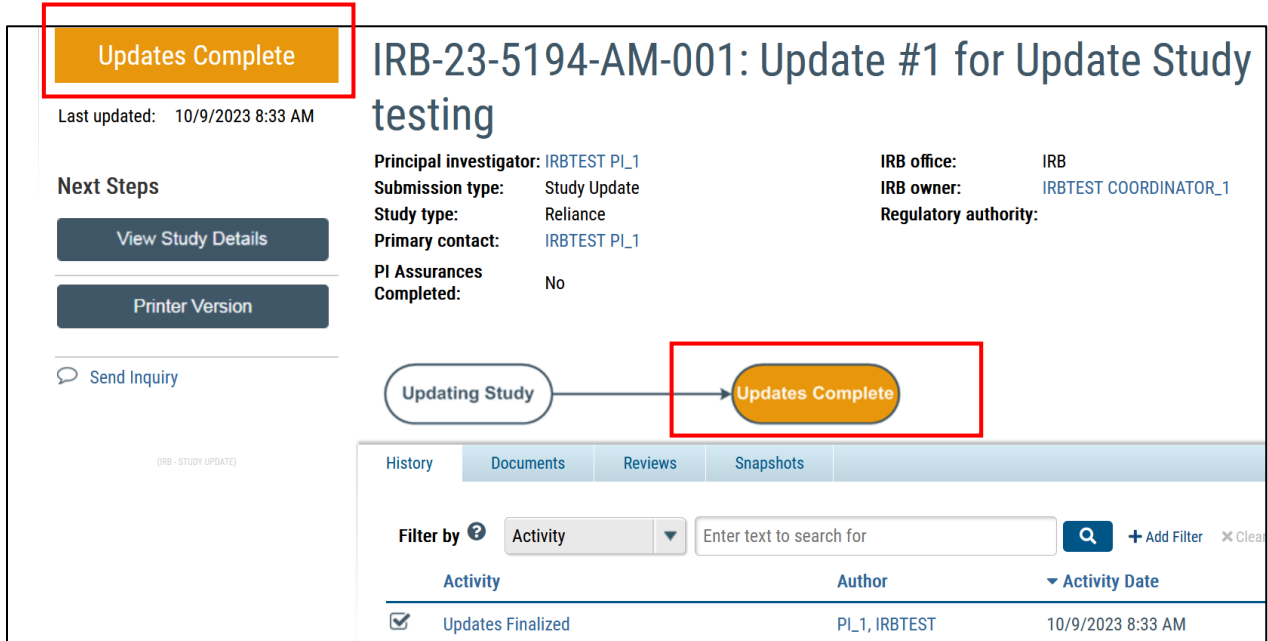
Once in the main study page, select *Finalize Updates* activity to complete this action.

The screenshot shows the BruinIRB web application interface for the study 'IRB-23-5194-AM-001: Update #1 for Update Study testing'. The page is titled 'Updating Study' and shows the last updated time as '10/6/2023 11:14 AM'. The 'Next Steps' sidebar includes 'Finalize Updates' (checked), 'Send Inquiry', and 'Discard'. The main content area displays study details: Principal investigator: IRBTEST_PL_1, Submission type: Study Update, Study type: Reliance, Primary contact: IRBTEST_PL_1, PI Assurances Completed: No, IRB office: IRB, IRB owner: IRBTEST COORDINATOR_1, and Regulatory authority: [blank]. A progress indicator shows 'Updating Study' leading to 'Updates Complete'. The 'Finalize Updates' button in the sidebar is highlighted with a blue arrow.

You will receive the following confirmation:



Once the update is accepted, the amendment history will show Updates Finalized.



NOTE: The UPDATE STUDY DETAILS activity will not be accessible if there is an open amendment or study update in progress. If you cannot see the button, check the “Follow-on Submissions” tab in the main study page to confirm no other reviews are in process.