

VA Central IRB: Quarterly Webinar Duplicate Project Reconciliation

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Topics

- What is Project Reconciliation?
- Why are we reconciling projects?
- Which projects can be reconciled?
- How are projects reconciled?
- What happens to projects not eligible for reconciliation?

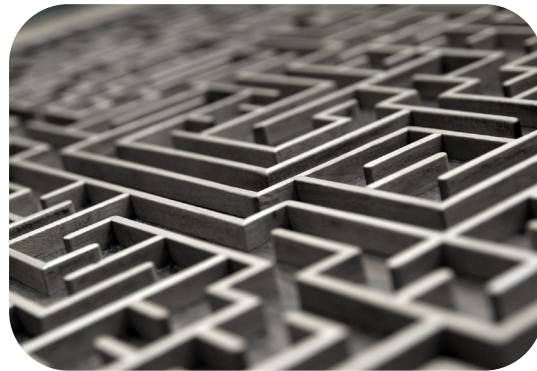
What is Project Reconciliation?

- VAMCs onboarded to IRBNet starting in February 2020
 - Most research programs uploaded active projects, including those projects under the oversight of the VA Central IRB (CIRB)
 - Created **local version** of CIRB projects
- CIRB onboarded to IRBNet in March 2021
 - CIRB uploaded ~1300 active projects
 - Created empty **CIRB project shells** (no documents)
 - In many cases, the CIRB project shell created a ‘duplicate’ project
 - New projects submitted after March 2021 do not have duplicate local versions
- Starting in April 2021, CIRB addressed the ‘duplicate’ projects by reconciling the **local version** of the project with the **CIRB project shell** (see ORD webinar archive)
 - Over 100 projects reconciled

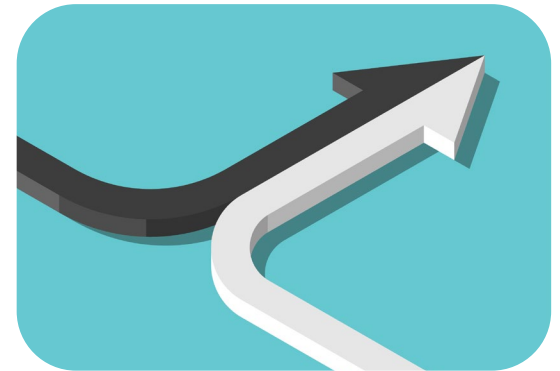
Why are we reconciling?



Reduce Confusion




Reduce Clutter in
IRBNet



Consolidate
Duplicate Projects

Projects Eligible for Reconciliation

- CIRB project shell must not have any subsequent study actions (packages greater than -1; does not include administrative packages such as PCS submissions) to reconcile the projects.



A screenshot of a project record in a system. The record ID is 1626173-1, which is circled in red. The project title is "Multi-site Feasibility of Compassion Meditati...". The status is "New Project", "EXP", and "Approved". The location is "19-22 Durham" and the date is "08/06/2021". There is a lock icon on the right. A large black checkmark is overlaid on the left side of the record. Below the main record, there are three smaller records: "Kendra Clarke...", "LSI Amendment...", and "Panel 1...".

-VS-



A screenshot of a project record in a system. The record ID is 1632789-4, which is circled in red. The project title is "CSP 2005, Veterans Affairs Lung Cancer Surger...". The status is "Continuing Review/ Progress Report", "EXP", and "Approved". The location is "16-19 Baltimore" and the date is "08/20/2021 10:00 AM". There is a lock icon on the right. A large black X is overlaid on the left side of the record.

How are projects reconciled?

Step	Description
Step 1	The duplicate project may be identified by the research office, PI/LSI study team, or the National Study Coordinator (NSC), Study Coordinator (SC), or Project Manager (PM). It is critical for the research office, NSC/SC/PM, and study team to communicate the desire to reconcile the duplicate project to ensure all parties are aware.
Step 2	The research office will submit request to the Central IRB via email identifying the duplicate IRBNet IDs.
Step 3	The CIRB will confirm the CIRB project shell is eligible for reconciliation. The CIRB project shell must not have any subsequent study actions (packages greater than -1; does not include administrative packages) to reconcile the projects. The CIRB will notify the requestor if the project is determined not eligible for reconciliation. If the project is eligible, the CIRB will notify the requestor and request the local project be submitted to the CIRB workspace. The IRB Manager is copied on all communication.

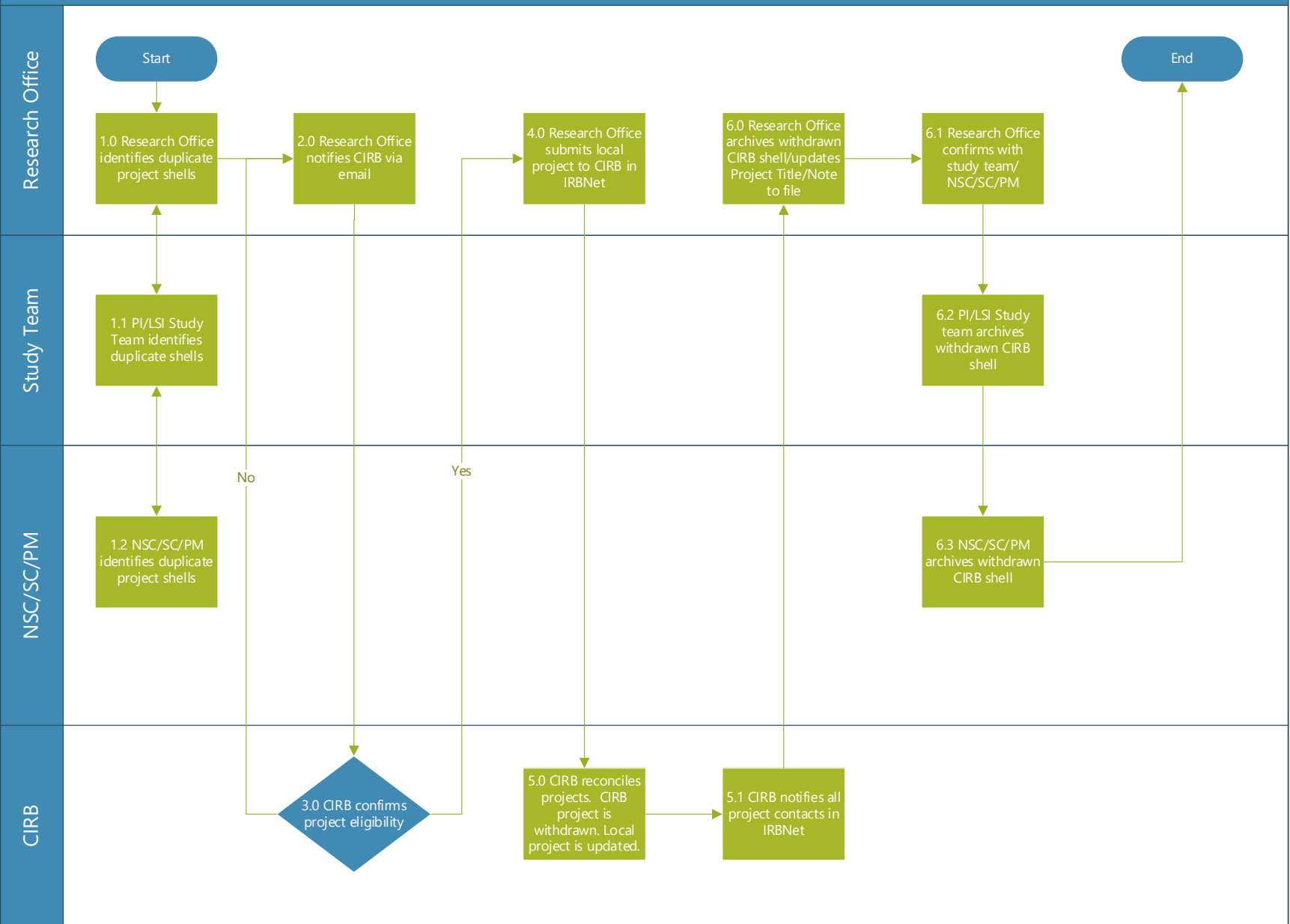
How are projects reconciled?

Step	Description
Step 4	The research office will create a new package (no study documents) in local version of project and submit the new package to the CIRB workspace. The submission type is 'Other' and the following submission note must be included: 'For Project Reconciliation'.
Step 5	<p>CIRB reconciles projects in IRBNet</p> <ul style="list-style-type: none">• Update local project with latest CIRB review details. Include remark referencing withdrawn CIRB shell IRBNet ID.• Withdraw CIRB shell. Include remark referencing local project IRBNet ID.• Unlink withdrawn CIRB shell from multi-site study, if applicable.• Link local project to multi-site study, if applicable.• Send Project Mail notifying all project contacts of completed reconciliation.

How are projects reconciled?

Step	Description
Step 6	<p>The research office completes the following steps:</p> <ul style="list-style-type: none">• Research office confirms reconciliation with study team.• Optional. Research office creates new package in withdrawn CIRB shell. The Project Title may be updated with 'ARCHIVED and DATE...' to ensure the project is not used going forward. The new package is submitted to the research administration workspace and updated with an Administrative review type, Acknowledged board action, Withdrawn project status, and no expiration date.• If shared as study team member, the research office archives the withdrawn CIRB shell.• PI/LSI study team archives withdrawn CIRB shell.• NSC/SC/PM archives withdrawn CIRB shell.

Central IRB (CIRB)/Local Shell Reconciliation Process



Projects not eligible for reconciliation

- **Option 1: Maintain local version of project and CIRB project**
 - Local version of project used for submissions to local committees
 - CIRB project used for submissions to CIRB
- **Option 2: Research Office withdraws local version**
 - Research Office withdraws local version with note to file for historical regulatory documents
 - Research office creates new package in local project. **Recommendation that the Project Title be updated with “ARCHIVED...*Project Title*..and ARCHIVED DATE...” to ensure the project is not used going forward.**
 - The new package is submitted to the research administration workspace and updated with an Administrative review type, Acknowledged board action, Withdrawn project status, and no expiration date.
 - Reconciliation notes recorded in Discussion/Remarks and Project Notes to include the active project IRBNet number

Availability of Recording

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Thank You for Attending!

Special Thanks to:

VA Central IRB Administrators and Managers

James Blankenship, IRB Administrator, Bay Pines VA Healthcare System

Jeff Newcomb, VA NODES Associate Director of Operations (Omaha, NE)