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External IRB Update Process Changes: Overview and Discussion

Office of Research Operations Lunch & Learn

February 24, 2026

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Overview & Discussion

- Background
  - External IRB Ground Rules
  - Structure: External IRB Submissions and the eIRB System
  - Type of Updates
- Pain Points
  - From the IRB
  - From the Research Community
- Overview: eIRB External IRB Update Standard Structure
- Possible Solutions
- Open Discussion

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Background

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External IRB Ground Rules

- The term “External IRB” is coined by the Huron eIRB system to differentiate studies reviewed by the DH IRB from those studies reviewed externally by another IRB.
- External IRB submissions are based on a reliance between institutions.
- Reliance requires:
  - *More than one institution is involved in the overall research.*
  - *All institutions involved in the research have an OHRP-approved Federalwide Assurance (FWA).*
  - *The institution is engaged in research activities.*
    - *Engagement is determined by the activities of the institution’s agents/affiliates, as well as whether direct federal funding is involved.*
    - *Activities that would engage the institution include: receiving a direct, federal award, consenting a study participant, intervening or interacting with a study participant, or obtaining private, identifiable information/biospecimen for research purposes.*
  - *The study is non-exempt. This means that the overall study has been reviewed at the expedited level or by the convened IRB. Overall, studies that have received a not research, not research with human subjects, or exempt determination do not qualify for reliance.*

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How the eIRB System Supports External IRB Submissions

Study-Wide

- Study-Wide Protocol/Reviewing IRB Protocol
- Template ICFs
- Template Recruitment Materials
- Overall IRB Study Approval
- Updates include CR and EXTUPDATE

Local-Site

- HRP-508 (Site Supplement)
- DH-Specific ICF
- DH-Specific Recruitment Materials
- HRP-215
- Ancillary Reviews, when applicable
- Updates include Site Modification

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Type of Updates

- Overall study continuing review approval
- Update to a study-wide document only (does not affect local site)
  - For example, a new IB that does not result in ICF changes
- Update to a study-wide document that affects the local site
  - For example, a new risk has been identified that changes the overall and local ICF
- Update to the local site only
  - A new DH study team member is added.

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Pain Points

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IRB Pain Points and **Current** Solution

The system does notify the IRB Analyst when an EXTUPDATE is created.

- *Revised the update process such that only site modifications are created by study teams. IRB Staff creates the EXTUPDATE to update the study-wide documents.*

To ensure compliance, match each document to the corresponding action.

- *Finalize and stamp study-wide and local-site documents.*

The system does not distinguish between study-wide and local-site Documents

- *Modifications: Stamp documents that were updated.*
- *Continuing Review: Stamp all study protocol, informed consent forms, and recruitment materials.*

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Study Team Pain Points

Revised the update process such that only site modifications are created by study teams. IRB Staff creates the EXTUPDATE to update the study-wide documents.

- *Study teams have to upload all study-wide documents as a comment.*

Finalize and stamp all documents.

- *The system stamps an approval end date and, therefore, documents that would not need to be uploaded again must be uploaded again.*

Others – we know there are more!

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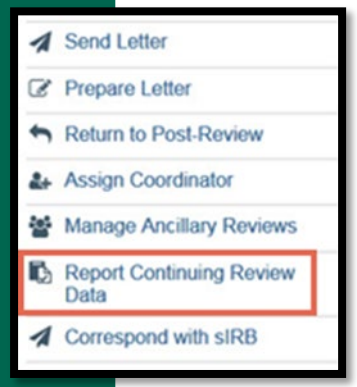
Overview:
eIRB External IRB Update Standard Structure

Standard Structure: Continuing Review

Study-Wide

- Click “Report Continuing Review Data.”
- *No edits made to the Study-Wide section.*
- Complete SmartForm.
- Upload HRP-212 - FORM - Continuing Review.
- Upload Reviewing IRB approval letter.
- Click “OK.”



Local-Site

- No changes needed.

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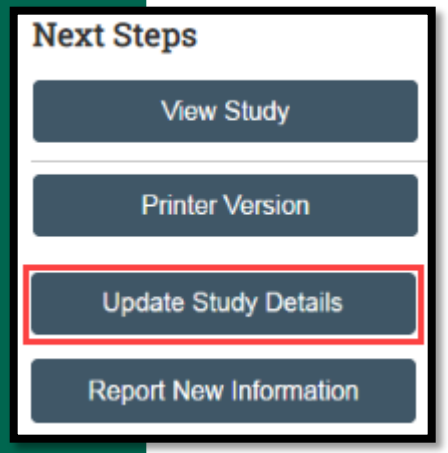
Standard Structure: Update Study-Wide Only

Study-Wide

- Click “Update Study Details.”
- *Can only edit “Study Wide” section*
- Complete SmartForm.
- Upload applicable documents.
- Upload Reviewing IRB approval letter.
- Click “OK.”
- You’ve just created an EXTUPDATE.



Local-Site

- No changes needed.

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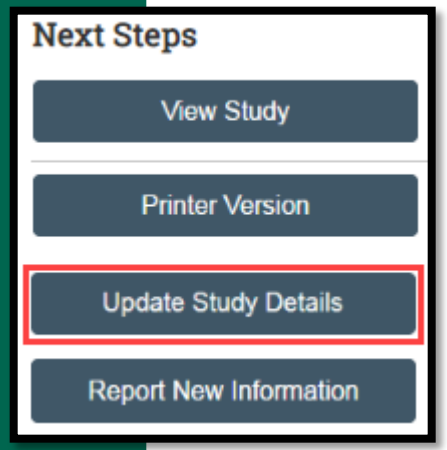
Standard Structure: Update Study-Wide and Local-Site

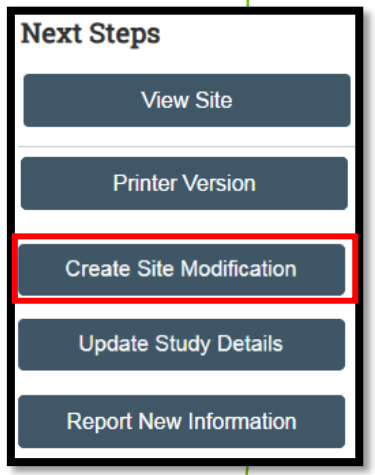
Study-Wide

- Click “Update Study Details.”
- *Can only edit “Study Wide” section*
- Complete SmartForm.
- Upload applicable documents.
- Upload Reviewing IRB approval letter.
- Click “OK.”
- You’ve just created an EXTUPDATE.



Local-Site

- Click “Create Site Modification.”
- Choose “Other Parts of Study”
- *Can only edit “Local Site” section.*
- Complete SmartForm.
- Upload applicable documents.
- If Reviewing IRB provided site-level approval, upload.
- Click “OK.”
- You’ve just created a “Modification.”



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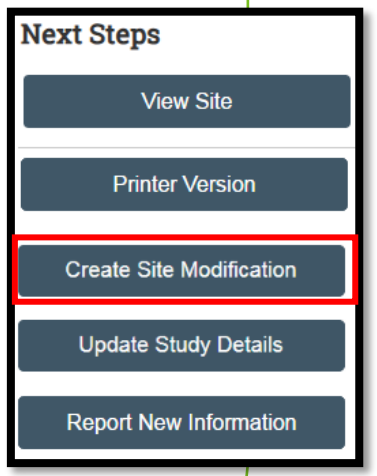
Standard Structure: Local-Site Only

Study-Wide

- No changes needed.

Local-Site

- Click “Create Site Modification.”
- Choose “Study team and research location information.”
- *Can only edit “Local Site” section.*
- Complete SmartForm.
- Make necessary revisions/ additions.
- Upload Reviewing IRB provided site-level approval.
- Click “OK.”
- You’ve just created a “Modification.”



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Possible Solutions

Move to using the standard process for updates

- Study Teams manage the study-wide section; IRB staff review only the local-site section.

Finalize and stamp only local-site documents.

- *Only stamp an effective date, not an approval end date.*
- *Create a local-site document naming convention, for example, “DH recruitment”, “DH ICF”.*

What are some other ideas that you might have?

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Open Discussion

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Thank you.