REVIEWING IRB SUBMISSIONS
(HRPP Only- Staff Guide)

Table of Contents:

IMPORTANT

- There are "important" boxes throughout this document with information pertinent to the various steps within the review (all highlighted with this red color).

Browsers Currently Supported:

- Windows and Macintosh - Mozilla Firefox; Google Chrome

- **Do not** use Microsoft Internet Explorer or Microsoft Edge

When answering any questions throughout the system:

- All questions marked with a red asterisk require a response.

- If a response is changed on any question, and there is a '**clear**' option, **'clear' needs to be selected before changing to a different response** (this applies to ALL pages of the submission).

- When uploading a document, please disregard the **Show Advanced Option**.

Reviewing Documents:

- To review any document within a submission (e.g., view study, printer version, documents, snapshots), you will need to open each uploaded document.

Questions and/or Requests:

- For any questions related to Huron IRB (e.g., errors, technical support), follow the current standard business practices of emailing RAIS through Huron-help@brown.edu

    - *Note: we will be setting up a new ticket option for access requests.*

Acronym	Translation
CR	Continuing Review
IRBC	IRB Coordinator
Mod	Modification
MSS	Multi-Site Study
PI	Principal Investigator
pSite	Participating Site
RNI	Reportable New Information
sIRB	Single IRB
SS	Single-Site Study

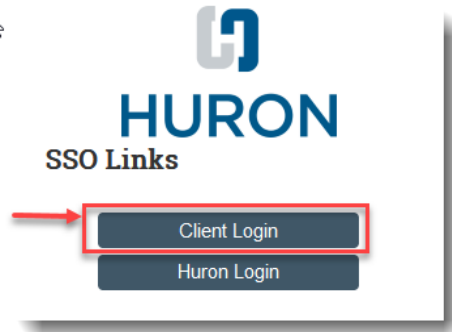| LOGIN	
Step	**Action & Screenshot**
	IMPORTANT There are 2 ways to log into Huron to view submissions. 1. Log in at the login page with your Brown credentials; or 2. Log in by clicking a link embedded in an email notification sent from the system. ● *Note: Not all action activities (e.g., submit study) will cause a notification to be sent to the HRPP office to know a submission is ready to review, as HRPP staff will be in the system already daily.*
1a	Log in here using your Brown credentials.
1b	Click on the link from within the email notification received, if applicable. ● *Note: if you are not logged in to Huron, you will automatically be directed to the login page.* ● *If you are not directed to the submission for review after logging in, see Step 2, below.*
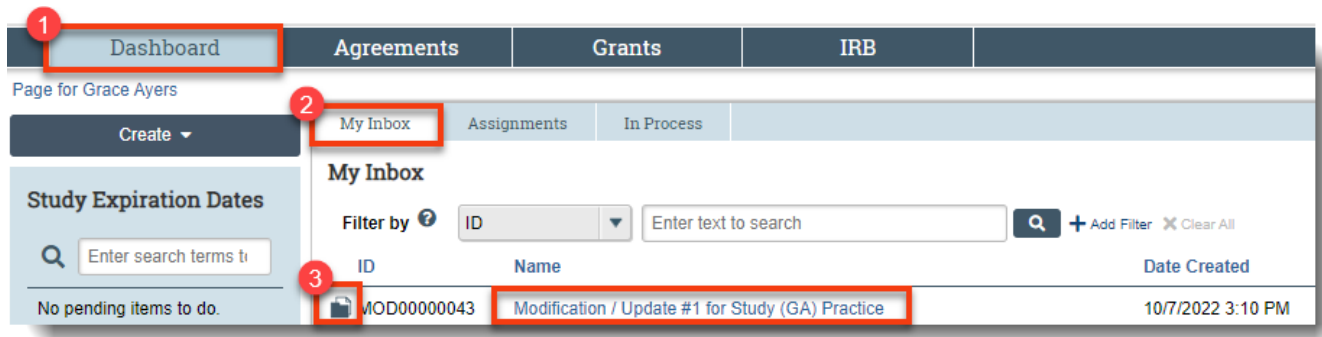
Initial Study Review
Submission Received

Step	Action & Screenshot
2	1. From the **Dashboard,** 2. Select **My Inbox**, and 3. Click on the **folder symbol (** 📁 **)** or the **Name** of the submission to open for review. ● *Note: recently submitted studies needing HRPP review will not have a coordinator listed and will be in a **Pre-Review** state.* ● *All submissions will be appear in every IRB Coordinator's (IRBC) **My Inbox**.* ● *The ID (protocol number) may read as STUDY, SITE, MOD, or RNI depending on what is being reviewed.*

PRE-REVIEW

Step	Action & Screenshot
3	To perform a pre-review, select: 1. **View Study**: opens the study and you can move through pages by clicking continue. ● *Note: to compare versions, the left side of the review will inform the reviewer if there were changes made throughout a submission. This may apply more for modification/CR reviews.* ● *If there is not a "no changes found" message, then click on the down-arrow to compare versions of a submission.*

Screenshot for Note

or

2. **Printer Version**: shows the smartform in one scrollable page.

3. **Documents**: provides all the attached study documents for review.

4. **Snapshots**: shows the smartform in one scrollable page.

   - *Note: within the above mentioned sections, you will need to open uploaded study documents within that section, as 1, 2, and 4 only open the smartform. Section 3 opens documents, but not the smartform.*

5. **Training**: CITI training for all study key personnel will be listed in this tab for HRPP review

4	After pre-review, staff will know if this is a multi-site study (MSS) or single-site study. If this is a MSS where there is external review, see [here](#). If this is a MSS with Brown as the IRB of record or this is a single-site study, select:

1. **Submit Pre-Review:** submit the initial study review determinations to move the study through the workflow to the IRB coordinator. The study will now be in the **IRB Review** state.

   - *Note: this step needs to be completed before the assigned coordinator reviews the study to close out the pre-review state and move it through workflow. The pre-review can be edited after submitted, if needed.*

2. **Request Pre-Review Clarification**: send a clarification request to the PI/Proxy/Primary Contact, if needed.

3. **Assign Coordinator**: the coordinator will take ownership of the study review, and will appear on reports and assignments.

   - *Note: the assigned coordinator can be changed at any point in the submissions life (e.g., can be changed following approval)*

4. **Assign Primary Contact:** the primary contact assigned by the PI and/or IRBC will receive notifications regarding the study (e.g., clarifications)

5. **Assign PI Proxy:** the PI proxy either is assigned by the PI or IRBC and they have permissions to view and edit the study, being the PI delegate

6. **Assign IRB:** if the study needs board review, choose the IRB office to review the study.

7. **Manage Ancillary Reviews**: allows individuals and/or organizations to give feedback on the submission (e.g., COI review).

8. **Manage Guest List:** individuals are added to a study to view including reviewer notes, but not private comments.

9. **Add Related Grant: (function will be available when grants/agreements go-live)** if a grant is associated with a study, it can be added at any time.

10. **Add Comment**: add any comments to be kept in the History of a study record and there is an option to also send these comments directly through the system to various groups (e.g., PI, IRBC).

    - *Note: **This action will not retain the reviewer's anonymity.** All comments will be saved to the submission history and anyone with access to the submission will be able to view them.*

11. **Withdraw**: withdraw the submission

12. **Discard**: remove the submission and it will be moved to Archived tab

13. **Manage Tags**: add tags to a study to pull them into a report

Next Steps

View Study

Printer Version

1. ☑ Submit Pre-Review
2. ↩ Request Pre-Review Clarification
3. 👤+ Assign Coordinator
4. 👤+ Assign Primary Contact
5. 👤+ Assign PI Proxy
6. 👥 Assign IRB
7. 👥 Manage Ancillary Reviews
8. 👥 Manage Guest List
9. ⊞ Add Related Grant
10. 💬 Add Comment
    📋 Copy Submission
11. ← Withdraw
12. ⊘ Discard
13. ⚙ Manage Tags

Assigned Coordinator Actions

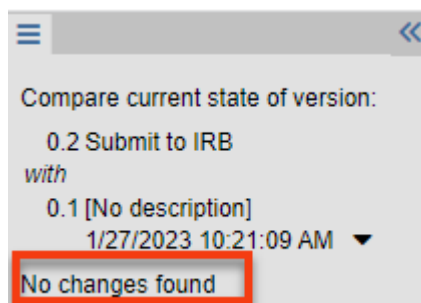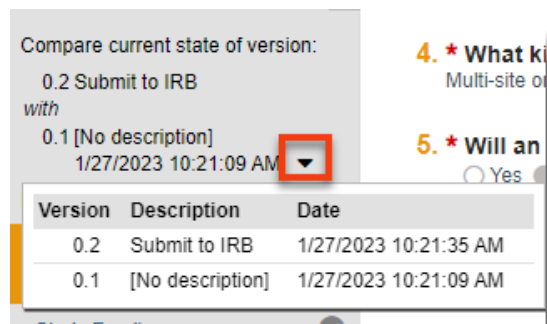| **5** | The Assigned Coordinator reviews by selecting:

1. **View Study**: opens the study and you can move through pages by clicking continue.

    ● *Note: To compare versions, the left side of the review will inform the reviewer if there were changes made throughout a submission. This may apply more for modification/CR reviews.*

    ● *If there is not a "no changes found" message, then click on the down-arrow to compare versions of a submission.*

Screenshot for Note |

2. **Printer Version**: shows the smartform in one scrollable page.

3. **History**: includes a history of all action items taken and communications sent for the entire life of the study

4. **Documents**: provides all the attached study documents for review.

5. **Sites**: if the study is a multi-site study, the participating sites will be listed and a [record will be created for review.](#)

6. **Reviews**: pre-reviews are captured in this location (and all committee and non-committee reviews following their determinations).

7. **Snapshots**: shows the smartform in one scrollable page.

6	The actions the Assigned Coordinator can make:
	
	1. **Assign Designated Reviewer:** assign the reviewer that provides study determinations (e.g., approval) through non-committee review (e.g., expedited review, exempt review), after initial review.
	
	2. **Assign to Meeting**: the study is assigned to a meeting, if the study needs committee review (e.g., full board)
	
	3. **Edit Pre-Review**: to make corrections to the original pre-review determinations, if needed.
	
	    ● *Note: this selection only appears after you click **Submit Pre-Review**.*
	
	4. **Add Participating Sites**: add participating sites (or additional sites not added by the PI) for a multi-site study.
	
	5. **Assign Coordinator**: the coordinator will take ownership of the study review, and will appear on reports and assignments.
	
	    ● *Note: the assigned coordinator can be changed at any point in the submission's life (e.g., can be changed following approval)*

6. **Assign Primary Contact:** the primary contact assigned by the PI and/or IRBC will receive notifications regarding the study (e.g., clarifications)

7. **Assign PI Proxy:** the PI proxy either is assigned by the PI or IRBC and they have permissions to view and edit the study, being the PI delegate

8. **Manage Ancillary Reviews**: allows individuals and/or organizations to give feedback on the submission (e.g., COI review).

9. **Manage Guest List:** individuals are added to a study to view including reviewer notes, but not private comments.

10. **Add Related Grant: (function will be available when grants/agreements go-live)** if a grant is associated with a study, it can be added at any time.

11. **Add Comment**: Add any comments to be kept in the History of a study record and there is an option to also send these comments directly through the system to various groups (e.g., PI, IRBC).

    - *Note: **This action will not retain the reviewer's anonymity.** All comments will be saved to the submission history and anyone with access to the submission will be able to view them.*

12. **Add Private Comment**: private comments may be sent to other members of the HRPP team and/or IRB directly through Huron.

    - *Note: private comments are not visible in History to the PI and study team.*

13. **Discard**: remove the submission and it will be moved to Archived tab

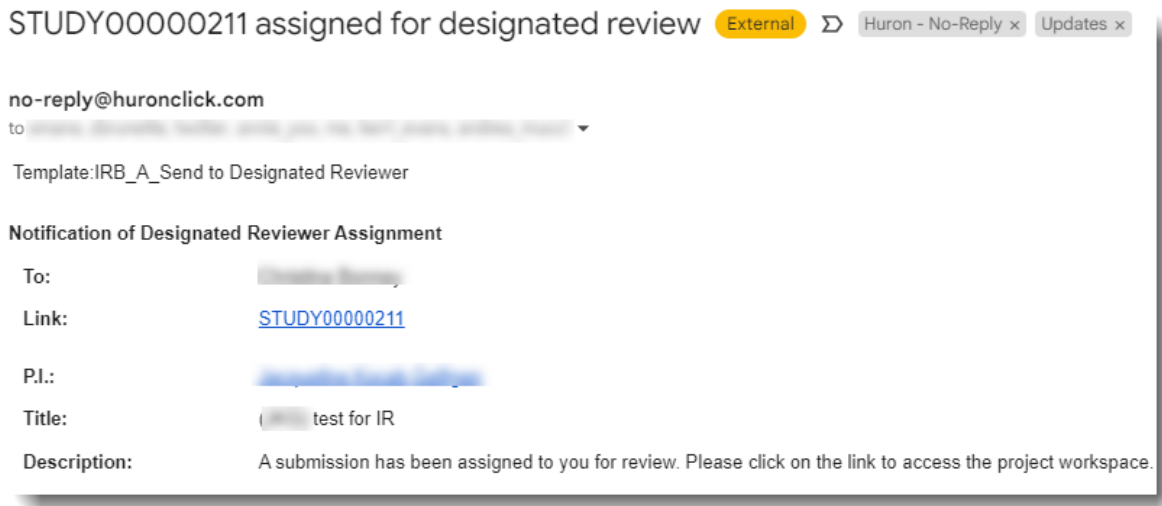14. **Manage Tags**: add tags to a study to pull them into a report
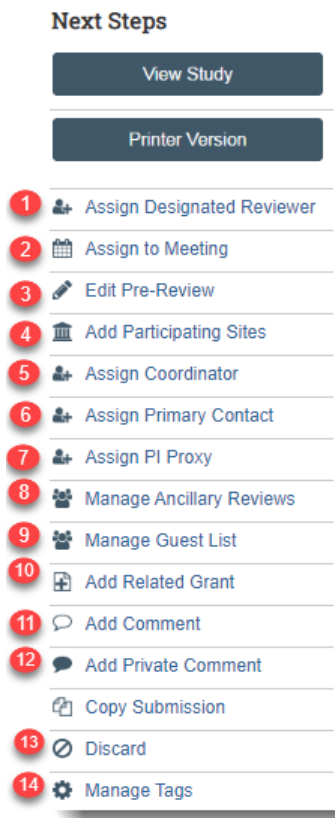
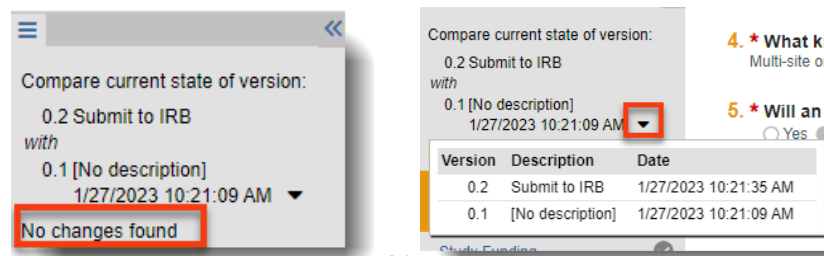|	**Assigned Designated Reviewer Actions** **NON-COMMITTEE REVIEW**

7a	If the study is to be reviewed by non-committee review procedures as a designated reviewer was assigned, they will receive an email notification that a study is ready for their review.
	
	If the assigned designated reviewer is not the same individual as the assigned coordinator, the designated reviewer should:
	
	   1. Click on either the **Link** provided within the email sent to their inbox,
	
	      or
	
	   2. If the reviewer is already logged into the system, <u>follow step 2</u> from Submission Received to open the study from the Dashboard with IRB Review as the state.
	
	STUDY00000211 assigned for designated review External Σ Huron - No-Reply × Updates ×
	
	no-reply@huronclick.com
	to ⬤
	
	Template:IRB_A_Send to Designated Reviewer
	
	Notification of Designated Reviewer Assignment
	
	To:
	Link: STUDY00000211
	P.I.:
	Title: test for IR
	Description: A submission has been assigned to you for review. Please click on the link to access the project workspace.

8a	To perform an IRB review as the Assigned Designated Reviewer, select:
	
	   1. **Review Study**: opens the study and you can move through pages by clicking continue.
	
	      ● *Note: To compare versions, the left side of the review will inform the reviewer if there were changes made throughout a submission. This may apply more for modification/CR reviews.*
	
	      ● *If there this message does not appear, "no changes found" message, then click on the down-arrow to compare versions of a submission.*
	
	Screenshot for Note
	
	Compare current state of version:
	  0.2 Submit to IRB
	with
	  0.1 [No description]
	    1/27/2023 10:21:09 AM ▼
	No changes found
	
	Compare current state of version:
	  0.2 Submit to IRB
	with
	  0.1 [No description]
	    1/27/2023 10:21:09 AM ▼
	
	| Version
		Description	Date |
			| 0.2 | Submit to IRB | 1/27/2023 10:21:35 AM |
			| 0.1 | [No description] | 1/27/2023 10:21:09 AM |
			
			4. * What ki Multi-site o
			5. * Will an ○ Yes
			
			or

2. **Printer Version**: shows the smartform in one scrollable page.

3. **History**: includes a history of all action items taken and communications sent for the entire life of the study

4. **Documents**: provides all the attached study documents for review.

5. **Sites**: if the study is a multi-site study, the participating sites will be listed and a record will be created for review.

6. **Reviews**: pre-reviews are captured in this location.

7. **Snapshots**: shows the smartform in one scrollable page.

8. **Training**: CITI training for all study key personnel will be listed in this tab for HRPP review

| 9a | If the reviewer selects **Review Study**,
- [Optional] Click on the box next to **Above section has been reviewed** to serve as a placeholder during your review
  - *Note: The section reviewed now turns light green and the box has a checkmark*
  - *There is a section hidden from view (Final Page) but a checkbox still remains. This box can be completed, too.*

 |

10a	After review is complete and ready for a determination to be made:

After review is complete and ready for a determination to be made:

1. **Submit Designated Review**: to document all determinations of the study

   - *Note: once determinations are made, go to Finalize Documents and Submit Determination Letter section of this guide.*

*There are other actions available for the reviewer before they **Submit Designated Review**, if needed (see below):*

2. **Assign Designated Reviewer**: if the designated reviewer needs to change (e.g., someone is on vacation, accidentally chosen), the reviewer can be reassigned.

3. **Assign to Committee Review**: if the study needs committee review instead of being reviewed by expedited or exempt procedure, the workflow can change to the appropriate review type

4. **Edit Pre-Review**: to make corrections to the original pre-review determinations, if needed.

   - *Note: all edited pre-reviews are recorded in the Reviews tab within the study record.*

5. **Add Participating Sites:** add participating sites (or additional sites not added originally) for a multi-site study.

   - *Note: if new sites are added, the sites should be reviewed.*

6. **Assign Coordinator**: the coordinator will take ownership of the study review, and will appear on reports and assignments.

   - *Note: the assigned coordinator can be changed at any point in the submissions life (e.g., can be changed following approval)*

7. **Assign Primary Contact:** the primary contact assigned by the PI and/or IRBC will receive notifications regarding the study (e.g., clarifications)

8. **Assign PI Proxy:** the PI proxy either is assigned by the PI or IRBC and they have permissions to view and edit the study, being the PI delegate

9. **Manage Ancillary Reviews**: allows individuals and/or organizations to give feedback on the submission (e.g., COI review).

10. **Manage Guest List:** individuals are added to a study to view including reviewer notes, but not private comments.

11. **Add Related Grant: (function will be available when grants/agreements go-live)** if a grant is associated with a study, it can be added at any time.
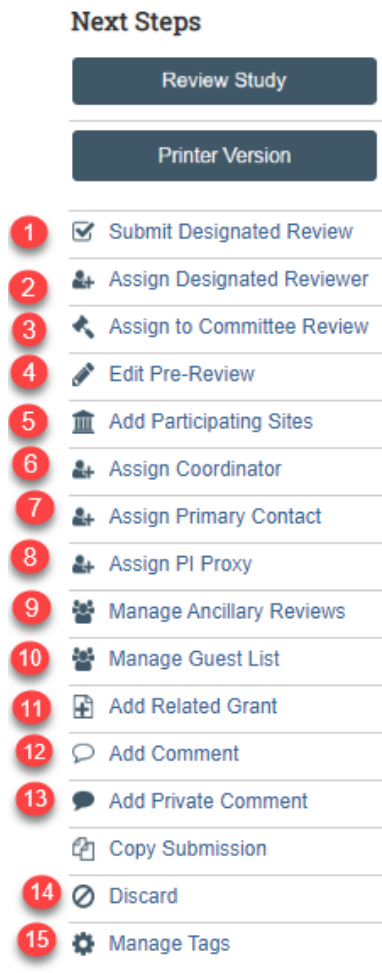
12. **Add Comment**: Add any comments to be kept in the History of a study record and there is an option to also send these comments directly through the system to various groups (e.g., PI, IRBC).

13. **Add Private Comment**: private comments may be sent to other members of the HRPP team and/or IRB directly through Huron.

- *Note: private comments are not visible in History to the PI and study team.*

14. **Discard**: remove the submission and it will be moved to Archived tab

15. **Manage Tags**: add tags to a study to pull them into a report.

Next Steps

	Review Study
	Printer Version
1	☑ Submit Designated Review
2	👤 Assign Designated Reviewer
3	🔨 Assign to Committee Review
4	✏ Edit Pre-Review
5	🏛 Add Participating Sites
6	👤 Assign Coordinator
7	👤 Assign Primary Contact
8	👤 Assign PI Proxy
9	👥 Manage Ancillary Reviews
10	👥 Manage Guest List
11	⊞ Add Related Grant
12	💬 Add Comment
13	💬 Add Private Comment
	🗐 Copy Submission
14	⊘ Discard
15	⚙ Manage Tags

11a	● Once review has been submitted, then the study moves to a Post-Review state and you can proceed to [Finalize Documents and Submit Determination Letter.](#)

Assigned to Meeting **COMMITTEE REVIEW**	
7b	To assign the study to a convened meeting: ● **Assign to Meeting**: assign the study to a scheduled meeting. ○ *Note: [See this review guide](#) on how to review the study at a convened meeting.*

8b	● Click **Review Study**
	● *Note: Anywhere there is an uploaded document within **Review Study**, click on the name of the document to open it.*
	● *If you select the (1) **Documents** tab within the open record, you can view (2) **Study Related Documents** and (3) **Site Related Documents**.*
	From 2nd Note:

9b	● Click **Review Site**, if this is a multi-site study within the Meeting
	● *Note: review the study and the site for multi-site studies*

	Committee Review Entered IRB: 10/25/2022 10:46 AM Last updated: 10/26/2022 9:20 AM **Next Steps** [Review Site] [Printer Version] ☑ Add Review Comments 💬 Add Comment 💬 Add Private Comment

10b	As a reviewer,
	
	● Click on the box next to **Above section has been reviewed** to serve as a placeholder during your review.
	
	    ○ *Note: The section reviewed now turns light green and the box has a checkmark*
	    ○ *There is a section hidden from view but a checkbox still remains. This checkbox can still be completed.*
	
	Above section has been reviewed: ☐

11b	● Once review is complete; click **Exit** ● *Note: you have now completed a submission review.* ⊗ Exit
12b	After convened meeting closes and determinations are made, select within a study record: ● **Submit Committee Review:** complete the form to record the committee's determination for the submission. ○ *Note: once the committee review is complete, go to Finalize Documents & Submit Determination Letter.* ☑ Submit Committee Review

Finalize Documents & Submit Determination Letter

IMPORTANT

If there is a pSite:

● Remember to review the pSite and move it through workflow.

    ○ *Note: how to review a pSite can be found here.*

● The pSite can only be approved following study approval.
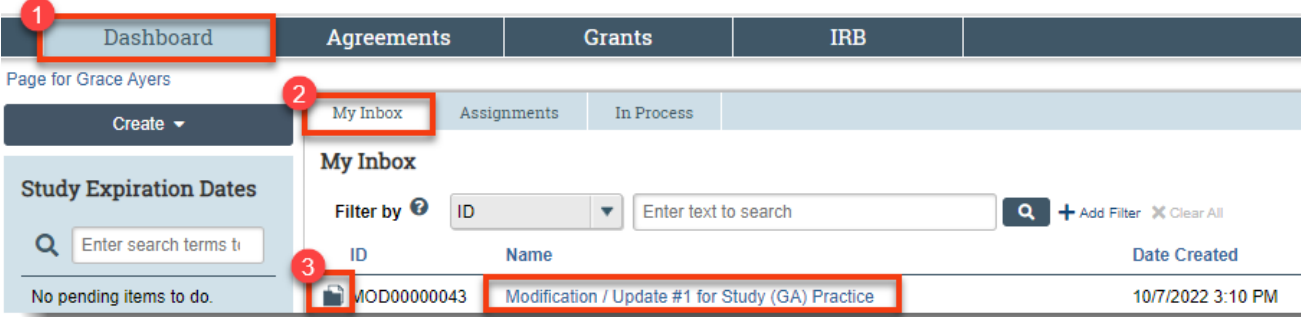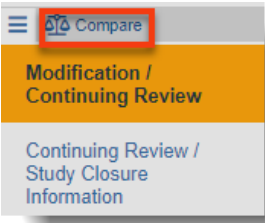
Once determinations are documented (non-convened or convened meetings), the IRBC can:

1. **Finalize Documents**: watermark the documents essentially stamping them before sending

   - *Note: Documents found in Other Documents will not be watermarked or finalized through the system.*

2. **Prepare Letter**: generate the letter to the PI / Proxy

3. **Send Letter**: send the determination letter to the PI / Proxy / Primary Contact

   - *Note: Send Letter only appears in the workspace after the letter has been prepared.*
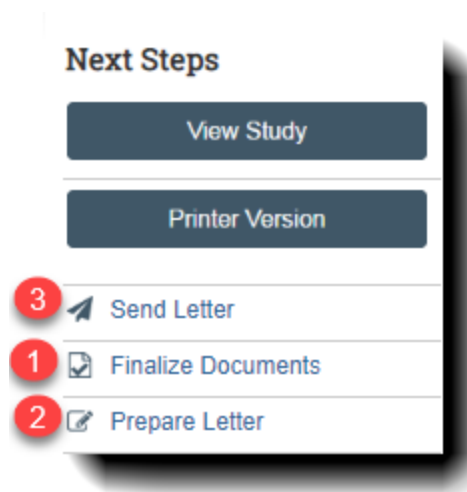
REVIEW OF MODIFICATION / CR	
Step	**Action & Screenshot**

1	1. From the **Dashboard,**
	
	2. Select **My Inbox**, and
	
	3. Click on the **folder symbol (** 📁 **)** or the **Name** of the submission to open for review
	
	    ● *Note: recently submitted studies needing HRPP review will not have a coordinator listed and will be in a **Pre-Review** state.*
	
	    ● *All submissions will be appear in every IRB Coordinator's (IRBC) **My Inbox***
	
	    ● *The ID (protocol number) will read as MOD or CR.*

2	Once in the study record, to perform a pre-review, select: 1. **View Modification/CR**: opens the study and you can move through pages by clicking continue. ● *Note: To compare versions, click Compare at the top left side toolbar* *Screenshot for Note* 2. **Printer Version**: shows the smartform in one scrollable page. 3. **Documents**: provides all the attached study documents for review. 4. **Snapshots**: shows the smartform in one scrollable page. 5. **Training**: CITI training for all study key personnel will be listed in this tab for HRPP review
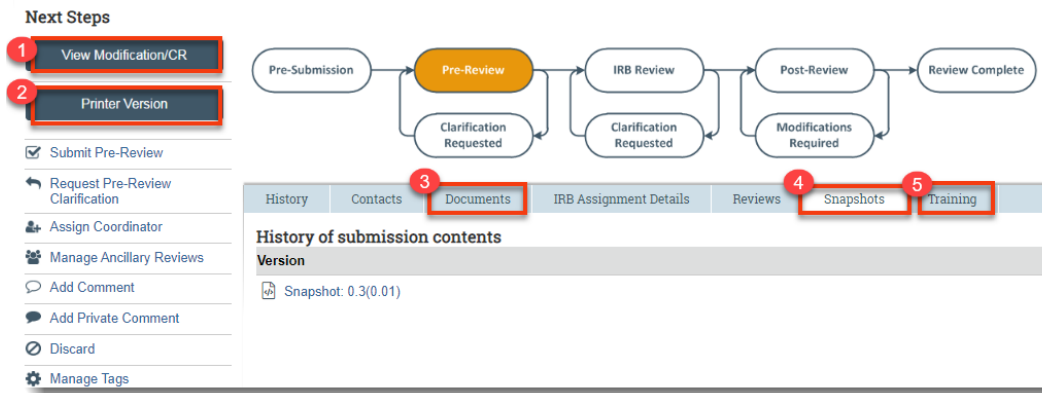
3	After pre-review, select:

1. **Submit Pre-Review:** submit the initial study review determinations to move the study through the workflow to the IRB coordinator. The study will now be in the **IRB Review** state.

   - *Note: this step needs to be completed before the assigned coordinator reviews the study to close out the pre-review state and move it through workflow. The pre-review can be edited after submitted, if needed.*

2. **Request Pre-Review Clarification**: send a clarification request to the PI/Proxy/Primary Contact, if needed.

3. **Assign Coordinator**: the coordinator will take ownership of the study review, and will appear on reports and assignments.

   - *Note: the assigned coordinator can be changed at any point in the submission's life (e.g., can be changed following approval)*

4. **Manage Ancillary Reviews**: allows individuals and/or organizations to give feedback on the submission (e.g., COI review).

5. **Add Comment**: Add any comments to be kept in the History of a study record and there is an option to also send these comments directly through the system to various groups (e.g., PI, IRBC).

   - *Note:* ***This action will not retain the reviewer's anonymity.*** *All comments will be saved to the submission history and anyone with access to the submission will be able to view them.*

6. **Add Private Comment**: private comments may be sent to other members of the HRPP team and/or IRB directly through Huron.

   - *Note: private comments are not visible in History to the PI and study team.*

7. **Discard**: remove the submission and it will be moved to Archived tab

8. **Manage Tags**: add tags to a study to pull them into a report

4	After pre-review is submitted, the study can be go to non-committee or committee review, and/or the pre-review can be edited:
	
	1. **Assign Designated Reviewer**: if the designated reviewer needs to change (e.g., someone is on vacation, accidentally chosen), the reviewer can be reassigned.
	
	   • *Note: If this study is to be reviewed by non-committee review, [follow these steps](#) to complete this review after selecting **Assign Designated Reviewer**.*
	
	2. **Assign to Committee Review**: if the study needs committee review instead of being reviewed by expedited or exempt procedure, the workflow can change to the appropriate review type
	
	   • *Note: If this study is to be reviewed by committee review, [follow these steps](#) to complete this review after selecting **Assign to Committee Review**.*
	
	3. **Edit Pre-Review**: to make corrections to the original pre-review determinations, if needed.
	
	   • *Note: all edited pre-reviews are recorded in the **Reviews** tab within the study record.*

<table>
<tr><td colspan="2" align="center">**IMPORTANT**</td></tr>
<tr><td colspan="2">

● RNI from a pSite, where Brown is the IRB of record, follows the same review process as a SS RNI

    ○ *Note: the Brown lead PI will be entering the RNI into the system on behalf of the collaborating PI from the pSite*

● RNI, when study is externally reviewed, follows <u>this</u> procedure.
</td></tr>
<tr><td colspan="2" align="center">**REVIEW OF RNI**</td></tr>
<tr><td>**Step**</td><td align="center">**Action & Screenshot**</td></tr>
<tr>
<td align="center">1</td>
<td>

From the **Dashboard**,

   1. Select **My Inbox**, and

   2. Click on the folder symbol (📁) or the **Name** of the submission to open for review

     ● *Note: recently submitted studies needing HRPP review will not have a coordinator listed and will be in a Pre-Review state.*

     ● *All submissions will be appear in every IRB Coordinator's (IRBC) My Inbox*

     ● *The ID (protocol number) will read as RNI.*

</td>
</tr>
<tr>
<td align="center">2</td>
<td>

Once in the study record, to perform a pre-review, select:

   1. **View RNI**: opens the study and you can move through pages by clicking continue.

     ● *Note: To compare versions, click Compare at the top left side toolbar*

Screenshot for Note

   2. **Printer Version**: shows the smartform in one scrollable page.
</td>
</tr>
</table>

3. **Documents**: provides all the attached study documents for review.

4. **Related Submissions**: any studies linked to the RNI will be found and can be reviewed, if needed.

3 | The IRBC can select,

5. **Submit RNI Pre-Review**: record pre-review determinations

6. **Request Pre-Review Clarification:** send a clarification request to the PI/Proxy/Primary Contact, if needed.

7. **Assign Coordinator**: the coordinator will take ownership of the study review, and will appear on reports and assignments.

   - *Note: the assigned coordinator can be changed at any point in the submission's life (e.g., can be changed following approval)*

8. **Assign IRB:**

9. **Manage Ancillary Reviews**: allows individuals and/or organizations to give feedback on the submission (e.g., COI review).

10. **Manage Editors:** editors can edit the details of the RNI, submit it for review and submit responses back to the HRPP/IRB to a clarification request, and submit action responses.

11. **Add Related Submissions:** relate the RNI to any of the PIs studies

12. **Add Comment**: Add any comments to be kept in the History of a study record and there is an option to also send these comments directly through the system to various groups (e.g., PI, IRBC).

13. **Add Private Comment**: private comments may be sent to other members of the HRPP team and/or IRB directly through Huron.

   - *Note: private comments are not visible in History to the PI and study team.*

14. **Discard**: remove the submission and it will be moved to Archived tab

15. **Manage Tags**: add tags to a study to pull them into a report

	Once the pre-review is submitted, the study moves into the Acknowledged state and the workflow is Review Complete 	
4		
5	The IRBC can, ● **Prepare Letter** to be sent to the PI/Proxy/Primary Contact 	

6	● **Send Letter** to be sent to the PI/Proxy/Primary Contact
	Next Steps View RNI Printer Version ☑ Submit RNI Pre-Review ✈ Send Letter ✎ Prepare Letter

	SITE REVIEW (Multi-Site Study)
	Brown is the IRB of Record
Step	**Action & Screenshot**

1	As Assigned Coordinator and/or IRBC, select:
	
	1. **Sites** within an open study record to review
	    a. Click on the **Name** of the Site to open the site documents for review; **or**
	
	    b. Click on the pencil/paper icon to open up the individual Site Review **SmartForm** documents
	
	    ● *Note: (b) opens up the Site SmartForm for editing, while (a) brings you to the Site workspace*
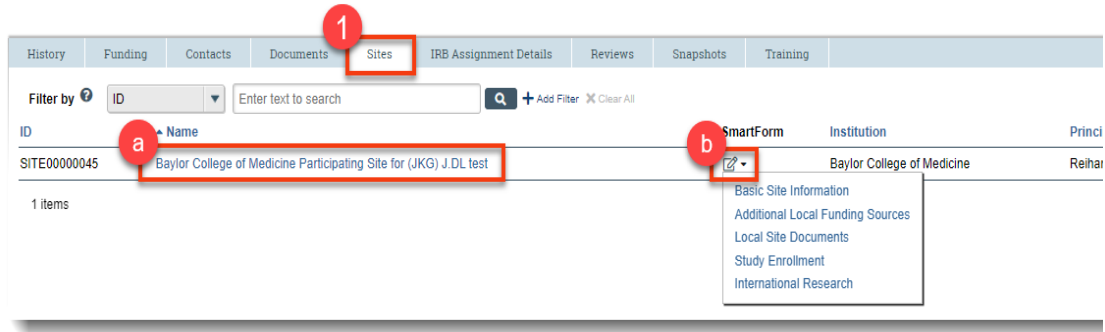
2	Select, ● **Edit Site**: the human research components taking place at the other site are not complete in the system to move this through workflow. ● *Note: if a site remains in the state of Invitation Pending when the RNI comes through for that site, there will be no option to select the correct site as the site has not yet been approved.*

IMPORTANT
● There are other actions available for the reviewer before they **Submit Invitation Decision**, if needed.   ● **Do not select Correspond with Site**, as collaborating investigators from outside institutions do not have access to Brown University's Huron IRB module.   ● Communications from outside institutions can be uploaded to **Record Response**.

3	● **Submit Invitation Decision:** to determine if the pSite is active or inactive in this study meeting the criteria to participate in this research. ● *Note: If the reviewer responds 'yes' the pSite will be active, but if they respond with 'no' to "does the site meet the criteria to participate in this research study," the pSite becomes inactive.*
4a *(if no, go to 4b)*	If Site is active (Submit Invitation Decision was 'yes'), ● **Submit Site Materials**: to confirm that all site-specific materials have been received.

- *Note: with the site meeting study meeting the criteria to participate in this research study, the site needs to be reviewed by an assigned designated reviewer, IRBC, or IRB.*

Next Steps

| Edit Site |
| Printer Version |
| ☑ Submit Site Materials |
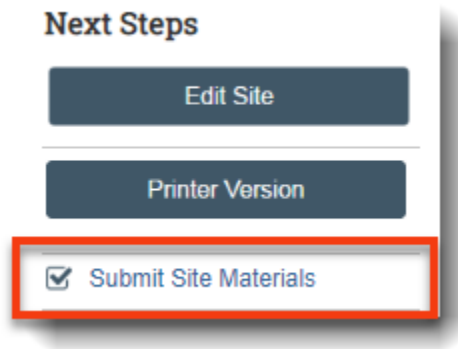
5a	If site is active and site materials were submitted, the reviewer may select,

1. **Assign Coordinator**: if different from the coordinator assigned to the original study, as this individual will be pulled into reports and seen on the IRB and Dashboard tables as the IRBC.

2. **Assign Designated Reviewer**: if different than the IRBC, this individual will be notified that they need to review and provide the determination on the pSite.

3. **Assign to Committee Review**: If the site needs IRB review, assign it to committee review.

Next Steps

| Review Site |
| Printer Version |
| ☑ Submit Site Designated Review |
| 2 ⊕ Assign Designated Reviewer |
| 3 ⚒ Assign to Committee Review |
| 1 ⊕ Assign Coordinator |
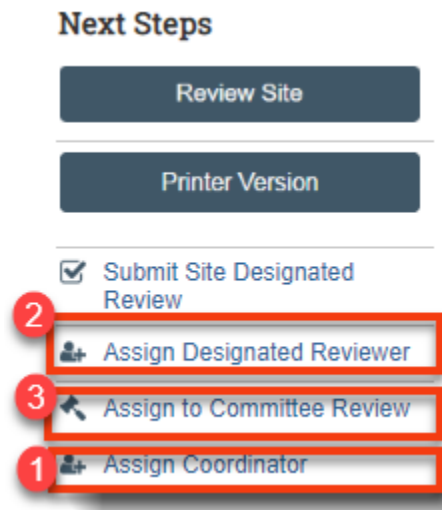
Assigned Designated Reviewer Actions **NON-COMMITTEE REVIEW**

6a	To review the site from either committee or non-committee review, select, 1. **Review Site**: opens the study and you can move through pages by clicking continue.

- *Note: To compare versions, the left side of the review will inform the reviewer if there were changes made throughout a submission. This may apply more for modification/CR reviews.*

- *If the "no changes found" message does not appear, then click on the down-arrow to compare versions of*

a submission.

Notes Screenshots
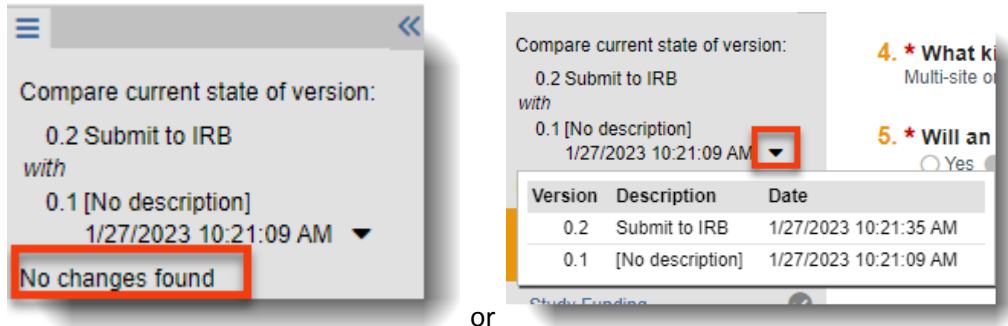
or

- *Changes can also be noted from the pencil icon next to the page view*
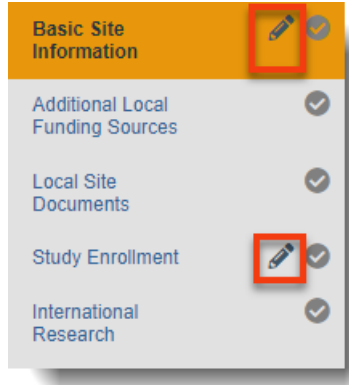
2. **Printer Version**: shows the smartform in one scrollable page.

3. **History**: includes a history of all action items taken and communications sent for the entire life of the study

4. **Documents**: provides all the attached study documents for review for the overall study.

5. **Submit Site Designated Review**: submit site determinations.

   - *Note: this option is only available if the study was reviewed by non-committee procedure.*

   - *By submitting site designated review, it records the determination made for the pSite without preceding the determinations made to the study*
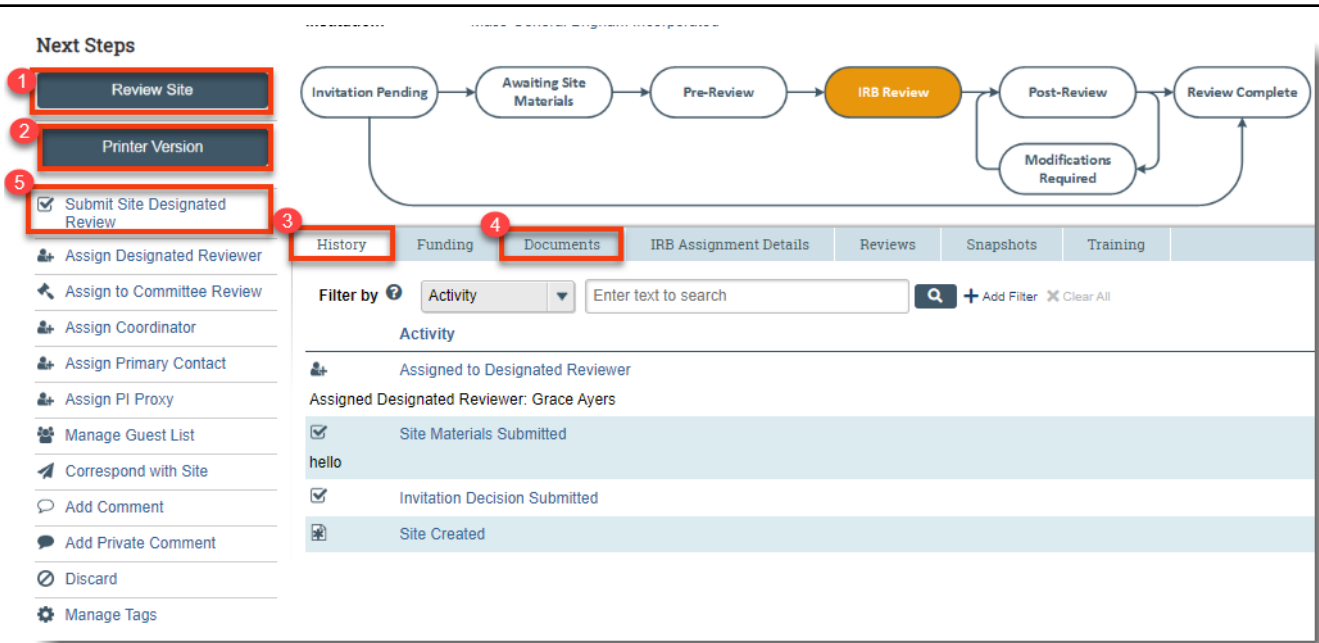
7a	If the reviewer selects **Review Site**, ● [Optional] Click on the box next to **Above section has been reviewed** to serve as a placeholder during your review ● *Note: The section reviewed now turns light green and the box has a checkmark* ● *There is a section hidden from view (Final Page) but a checkbox still remains. This box can be completed, too.*
8a	Once review is complete, select, ● **Submit Site Designated Review**: to complete the determinations made about the site review. ● *Note: The multi-site study has not yet been approved, even if the approved determination is chosen within the site review, as the review cannot be submitted until the study has been approved first.* ● ***To approve the site, the reviewer will need to come back to this step following study approval.***
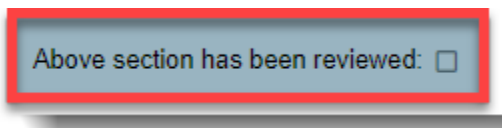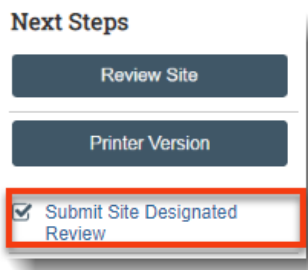
	COMMITTEE REVIEW
6b	If Assigned to Committee Review, ● **Assign to Meeting:** to place the Site on the agenda for committee review
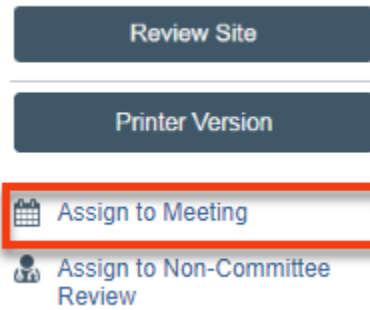
7b	After assigning to a meeting, and after the committee reviews the study,
	
	    ● **Submit Site Committee Review**: submit the committee's determination on the site following the IRB meeting.
	
	        ● *Note: if the study has not yet been approved for multi-site studies, data may be entered in this location; however, the review cannot be submitted until the study has been approved first.*
	
	        ● *To approve the site, the reviewer will need to come back to this step following study approval.*
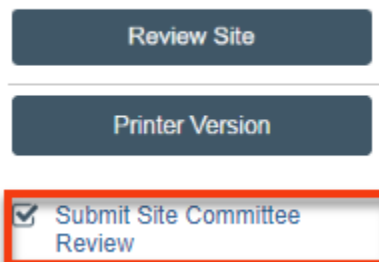
Finalize Documents & Submit Determination Letter

Once determinations are documented from the study by either non-convened or convened review, the IRBC can:

1. **Finalize Documents**: watermark the documents essentially stamping them before sending

2. **Prepare Letter**: generate the letter to the PI / Proxy

3. **Send Letter**: send the determination letter to the PI / Proxy / Primary Contact

    ● *Note: Send Letter only appears in the workspace after the letter has been prepared.*

4b	If Site is Inactive (Submit Invitation Decision was 'no') from Step 3,
	• **Record Response:** to include the reason for the decision, the external institution's communications and documents, if applicable.
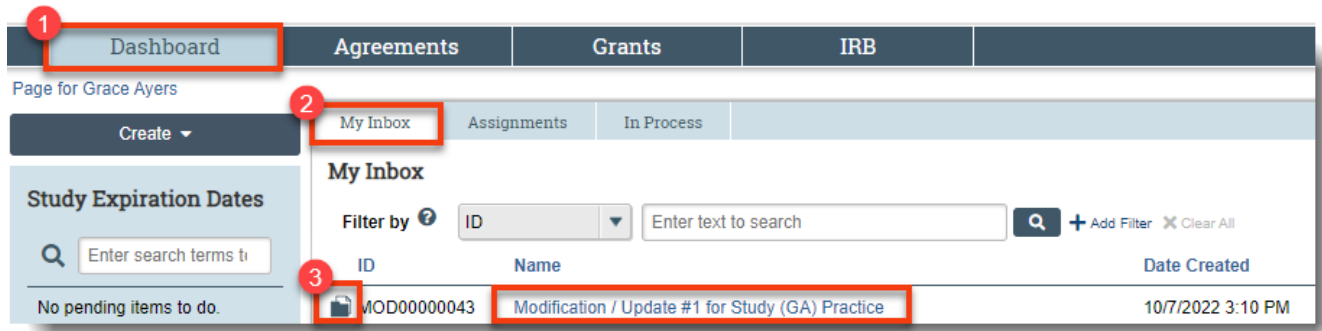
IMPORTANT	
	• Neither SS or MSS external IRB study use Huron's IRB Exchange. • To collect the information, HRPP will communicate with the external IRB and record all the communications and determinations using the **Record sIRB Decision** activity available.

	EXTERNAL STUDY REVIEW

1	1. From the **Dashboard,**
	
	2. Select **My Inbox**, and
	
	3. Click on the **folder symbol (** ☐ **)** or the **Name** of the submission to open for review
	
	   • *Note: recently submitted studies needing HRPP review will not have a coordinator listed and will be in a Pre-Review state.*
	
	   • *All submissions will be appear in every IRB Coordinator's (IRBC) My Inbox*

2	1. **View Study**: opens the study and you can move through pages by clicking continue.
	
	   • *Note: To compare versions, the left side of the review will inform the reviewer if there were changes made throughout a submission. This may apply more for modification/CR reviews.*
	
	   • *If there is not a "no changes found" message, then click on the down-arrow to compare versions of a submission.*
	
	or
	
	2. **Printer Version**: shows the smartform in one scrollable page.

3. **Documents**: provides all the attached study documents for review.

4. **Snapshots**: shows the smartform in one scrollable page.

   - *Note: within the above mentioned sections, you will need to open uploaded study documents within that section, as 1, 2, and 4 only open the smartform. Section 3 opens documents, but not the smartform.*

5. **Training**: CITI training for all study key personnel will be listed in this tab for HRPP review

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IMPORTANT

- <u>**Do not**</u> **select Correspond with Site**, as collaborating investigators from external institutions do not have access to Brown University's Huron IRB module.

3	After pre-review of this externally reviewed study, the HRPP may select:

1. **Confirm Reliance:** submit confirm reliance to move this study to an Active state indicating that their reliance agreement with the external institution is conducting the review.

    - *Note: If 'yes,' the site will be moved to the Pending sIRB Review state. If 'no,' the site is in an Inactive state.*

2. **Request Pre-Review Clarification**: send a clarification request to the PI/Proxy/Primary Contact, if needed.

3. **Assign Coordinator**: the coordinator will take ownership of the study review, and will appear on reports and assignments.

    - *Note: the assigned coordinator can be changed at any point in the submission's life (e.g., can be changed following approval)*

4. **Assign Primary Contact:** the primary contact assigned by the PI and/or IRBC will receive notifications regarding the study (e.g., clarifications)

5. **Assign PI Proxy:** the PI proxy either is assigned by the PI or IRBC and they have permissions to view and edit the study, being the PI delegate

6. **Assign IRB:** if the study needs board review, choose the IRB office to review the study.

7. **Manage Ancillary Reviews**: allows individuals and/or organizations to give feedback on the submission (e.g., COI review).

8. **Manage Guest List:** individuals are added to a study to view including reviewer notes, but not private comments.

9. **Add Related Grant: (function will be available when grants/agreements go-live)** if a grant is associated with a study, it can be added at any time.

10. **Add Comment**: Add any comments to be kept in the History of a study record and there is an option to also send these comments directly through the system to various groups (e.g., PI, IRBC).

    - *Note: **This action will not retain the reviewer's anonymity.** All comments will be saved to the submission history and anyone with access to the submission will be able to view them.*

11. **Add Private Comment**: private comments may be sent to other members of the HRPP team and/or IRB directly through Huron.

    - *Note: private comments are not visible in History to the PI and study team.*

12. **Discard**: remove the submission and it will be moved to Archived tab

13. **Manage Tags**: add tags to a study to pull them into a report

4	After reliance is confirmed, the IRBC may:
	
	1. **Edit Site**: edit the study, if necessary, to make sure all data is complete
	
	    ● *Note: the IRBC and PI can edit the site as long as the IRBC has not selected Record sIRB Decision*
	
	2. **Record sIRB Decision**: record the external review determination to keep all information in the system on the study (e.g., determination, common rule regulatory requirements, special determinations, regulatory oversight, risk level)
	
	    ● *Note: when recording the external IRBs determination, there is a field to upload their memos.*
	
	Screenshot of Note:
	
	    ● *Note:when you click into Record sIRB Decision, the last 2 questions will ask if the documents need to be finalized or a letter sent and if you are ready to record the sIRB's decision on the study. If 'yes,' to the first question (#12), documents can be finalized, letters can be sent to HRPP staff to move this study as Active, and if 'no,' the study just moves to an Active state without letters being finalized.*
	
	    ● *If 'yes' to the last question, the submission moves to Active and if 'no,' you can return and finish recording the decision at another time by clicking this activity again.*

12. * Do you need to finalize documents or send a letter? ❓
○ Yes ○ No *Clear*

13. * Are you ready to record the sIRB's decision? ❓
○ Yes ○ No *Clear*

🔒 hrspbrwnstage.huronclick.com/IRB/app/portal/HelpContent?ContentId=ContentFor_VIEW... 🔍

Finalize Documents or Send Letter

Yes moves the study to the Post-Review state so you can finalize study or site documents or send an acknowledgement letter to IRB staff before moving to the next state.

No moves a study to the External IRB state or a site to the Active state (provided you also confirm you are ready to record the sIRB's decision in the next question on this form).

Next Steps

1 Edit Site

Printer Version

2 ☑ Record sIRB Decision
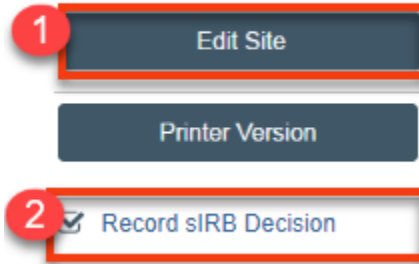
5	Once a reliance has been confirmed,

● If 'yes' to finalizing documents, the following activities will appear:

  ○ **Finalize Documents**: watermark the documents essentially stamping them before sending

  ○ **Prepare Letter**: prepare the acknowledgement letter for HRPP staff that the study and site are all set up.

    ■ *Note: once the letter is prepared, it can be sent to the PI (click Send Letter), or if HRPP would rather the letter does not need to go out, as the PI is receiving an approval from another institution on this research, the study can sit as is, and the letter stays within the History tab of the study record.*

Next Steps

View Site

Printer Version

☑ Finalize Documents
✎ Prepare Letter
✏ Edit sIRB Decision
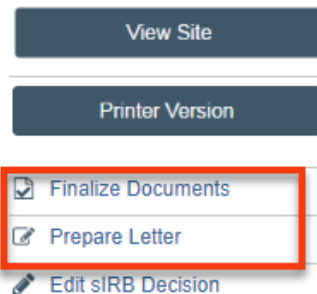
● If 'no' to finalizing documents, the following activities will appear:

  ● **Prepare Letter**: prepare the acknowledgement letter for HRPP staff that the study and site are all set up. |

○ *Note: once the letter is prepared, it can be sent to the PI (click Send Letter), or if HRPP would rather the letter does not need to go out, as the PI is receiving an approval from another institution on this research, the study can sit as is, and the letter stays within the History tab of the study record.*

● **Return to Post-Review**: if the submission needs edits before sending off the letter, then return it to post-review.
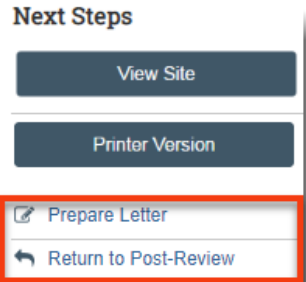
● The IRBC has the following new options at any time once a reliance was confirmed:
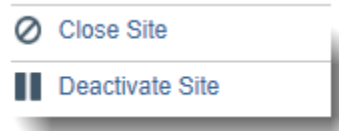
Site Modification Review
EXTERNAL STUDY

Step	Action & Screenshot
1	The study is now in an Active State. If the PI creates site modifications, updates study details, or reports continuing review data, the IRBC can: To perform a pre-review, select: 1. **View Modification**: opens the study modification and you can move through pages by clicking continue. ● *Note: To compare versions, the left side of the review will inform the reviewer if there were changes made throughout a submission. This may apply more for modification/CR reviews.* ● *If there is not a "no changes found" message, then click on the down-arrow to compare versions of a submission.*

2. **Printer Version**: shows the smartform in one scrollable page.

3. **Documents**: provides all the attached study documents for review.

4. **Related RNIs**: review any related RNIs for study to check for applicability to the modification

5. **Snapshots**: shows the smartform in one scrollable page.

   - *Note: within the above mentioned sections, you will need to open uploaded study documents within that section, as 1, 2, and 4 only open the smartform. Section 3 opens documents, but not the smartform.*

6. **Training**: CITI training for all study key personnel will be listed in this tab for HRPP review
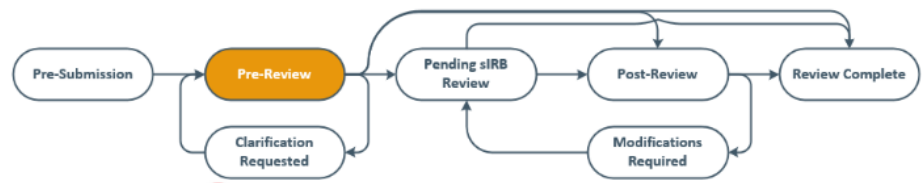
2	Once the review is complete of the modification from an externally reviewed study, - **Accept Site Updates**: accept/acknowledge the site modifications for historical purposes in the system.

3	• **Record sIRB Decision:** record the external review determination to keep all information in the system on the study (e.g., determination, common rule regulatory requirements, special determinations, regulatory oversight, risk level) • *Note: when recording the external IRBs determination, there is a field to upload their memos.* *Screenshot of Note:*

Site CR EXTERNAL STUDY	
Step	**Action & Screenshot**

1	If a PI reports continuing review data to their externally reviewed study, the IRBC will receive an emailed notification of this activity within the system.
	
	To review the updates,
	   1. Click on either the **Link** provided within the email sent to your inbox,
	
	       or
	
	   2. If the reviewer is already logged into the system, follow step 2 from the the Initial Study Review table

2	To view the CR data reported, within the study record workspace,
	1. Select **History**: 2. Click on the **Activity** labeled as Continuing Review Data Reported to view the new CR data
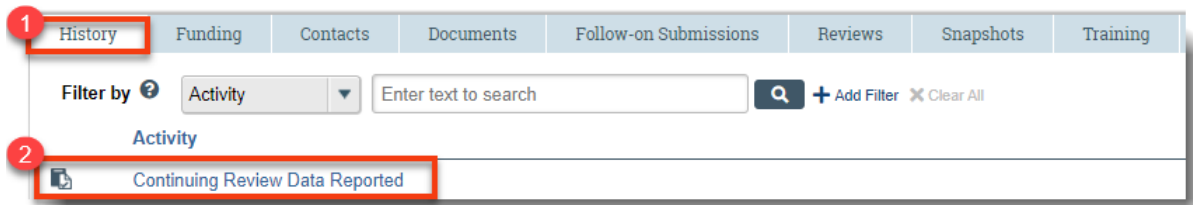
3	No further action is needed, as all updates are complete and the submission is in the **Active** state and the workflow is at **Review Complete**.

Site RNI Review EXTERNAL STUDY	
Step	**Action & Screenshot**
1	1. From the **Dashboard,** 2. Select **My Inbox**, and 3. Click on the **folder symbol (** 🗁 **)** or the **Name** of the submission to open for review ● *Note: recently submitted studies needing HRPP review will not have a coordinator listed and will be in a **Pre-Review** state.* ● *All submissions will be appear in every IRB Coordinator's (IRBC) **My Inbox*** ● *The ID (protocol number) will read as RNI*
2	To perform a pre-review of an RNI, select: 1. **View RNI**: opens the study RNI and you can move through pages by clicking continue. ● *Note: To compare versions, click Compare at the top left side toolbar* 2. **Printer Version**: shows the smartform in one scrollable page. 3. **Documents**: provides all the attached study documents for review. 4. **Related Submissions**: any studies linked to the RNI will be found and can be reviewed, if needed.
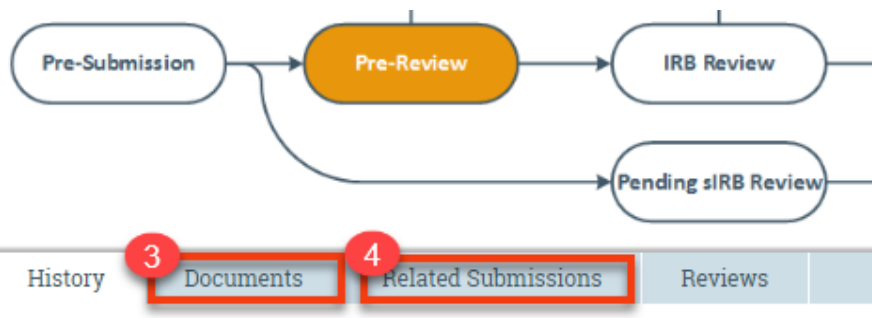
3	The IRBC can select,
	
	1. **Submit RNI Pre-Review**: record pre-review determinations
	
	2. **Request Pre-Review Clarification:** send a clarification request to the PI/Proxy/Primary Contact, if needed.
	
	3. **Route for sIRB Review**: if the RNI needs to be routed to the external site for review, this activity can be chosen
	    ● *Note: this activity will keep the submission in the correct workflow state of **Pending sIRB Review**.*
	
	    ● *There are no notifications sent through the system for this activity, but communication will need to be taken outside of the system with the external IRB and then recorded in **Record sIRB RNI Decision***

4a	If the RNI pre-review was submitted (**Submit RNI Pre-Review**), then new activities come available,
	
	1. **Assign Designated Reviewer**: if the designated reviewer needs to change (e.g., someone is on vacation, accidentally chosen), the reviewer can be reassigned.
	
	    ● *Note: the steps for non-committee review can be followed here.*
	
	2. **Assign to Meeting**: to place the Site on the agenda for committee review
	
	    ● *Note: the steps for committee review can be followed here.*
	
	3. **Assign Coordinator**: the coordinator will take ownership of the study review, and will appear on reports and assignments.

- *Note: the assigned coordinator can be changed at any point in the submissions life (e.g., can be changed following approval)*

4. **Manage Ancillary Reviews**: allows individuals and/or organizations to give feedback on the submission (e.g., COI review).

5. **Manage Editors:** editors can edit the details of the RNI, submit it for review and submit responses back to the HRPP/IRB to a clarification request, and submit action responses.

6. **Add Related Submissions:** relate the RNI to any of the PIs studies

7. **Add Comment**: Add any comments to be kept in the History of a study record and there is an option to also send these comments directly through the system to various groups (e.g., PI, IRBC).

   - *Note: **This action will not retain the reviewer's anonymity.** All comments will be saved to the submission history and anyone with access to the submission will be able to view them.*

8. **Add Private Comment**: private comments may be sent to other members of the HRPP team and/or IRB directly through Huron.

   - *Note: private comments are not visible in History to the PI and study team.*

9. **Discard**: remove the submission and it will be moved to Archived tab

10. **Manage Tags**: add tags to a study to pull them into a report.

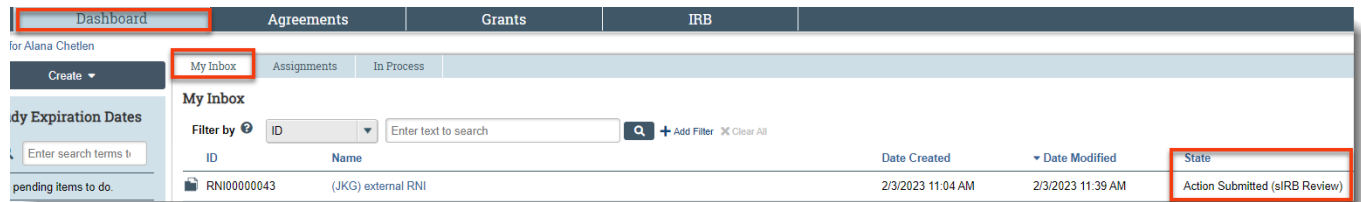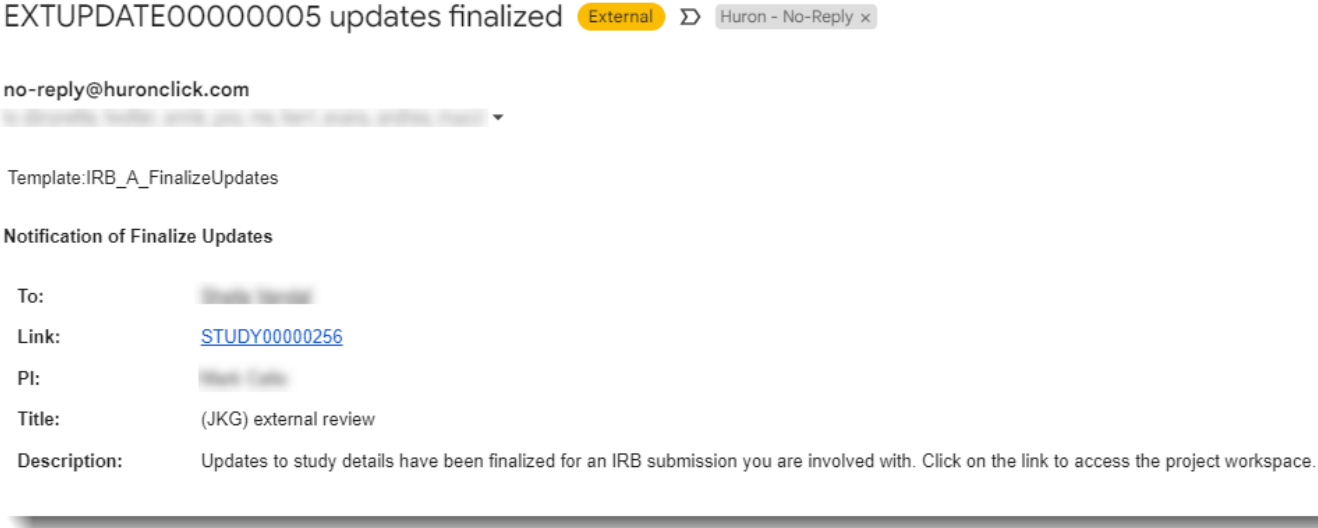|		

4b	If the RNI was routed to the sIRB for review,
	
	     ● **Record sIRB RNI Decision**: record the external IRB determinations on the RNI
	
	         ● *Note: if there is a responsible party to take further actions, the IRBC can note them and assign the RNI to that responsible party*
	
	         ● *The responsible party will receive an email notification that actions are needed to resolve the RNI*
	
	 Screenshot for Note:	

5b	If the responsible party submits their action responses, the IRBC will see in **My Inbox** from the **Dashboard**, the ID of RNIxxxxxxxx in the State of **Action Submitted (sIRB Review)**, which indicates it is ready for review.
	
	     ● *Note: the IRBC will need to send this outside of the system to the external IRB for review*
	
	     ● *The IRBC can record the external IRB's decision within this record with the activity of **Record sIRB RNI Decision***	

	IMPORTANT
	● For a MSS or a SS study externally reviewed, the local IRB is notified when the PI updates study details.
	● The updates will appear in the **Updates Complete** state
	○ *Note: HRPP can only view the updates; there are no actions unless the IRBC wants to add a comment due to a possible error in the updates.*

	Site Update Details **EXTERNAL STUDY**
Step	**Action & Screenshot**
1	If a PI submits study updates to their externally reviewed study, the IRBC will receive an emailed notification of this activity within the system. To review the updates, 3. Click on either the **Link** provided within the email sent to your inbox, *or* 4. If the reviewer is already logged into the system, follow step 2 from the the Initial Study Review table EXTUPDATE00000005 updates finalized External Σ Huron - No-Reply × no-reply@huronclick.com Template:IRB_A_FinalizeUpdates **Notification of Finalize Updates** To: Link: STUDY00000256 PI: Title: (JKG) external review Description: Updates to study details have been finalized for an IRB submission you are involved with. Click on the link to access the project workspace.
2	Once the submission is open, 1. Select **Follow-on Submissions** 2. Select the **ID** with **EXTUPDATE**xxxxxx

ID	Name	Date Modified	Owner	State
EXTUPDATE00000005	Update #1 for (JKG) external review	2/3/2023 12:53 PM		Updates Complete
RNI00000044	(JKG) RNI copied for external site	2/3/2023 12:36 PM		Non-Committee Review
RNI00000043	(JKG) external RNI	2/3/2023 11:39 AM		Action Submitted (sIRB Review)
MOD00000070	Modification / Update #1 for (JKG) external review	2/2/2023 4:33 PM		Pending sIRB Review

3	The State of this submission is Updates Complete, but to view the updates,

1. **View Study Details:** opens the details and you can move through pages by clicking continue.

2. **Printer Version**: shows the smartform in one scrollable page.

3. **Documents**: provides all the attached study documents for review.

4. **Snapshots**: shows the smartform in one scrollable page.

4	No further action is needed, as all updates have been finalized/complete and the State and workflow of the submission are both **Updates Complete**.