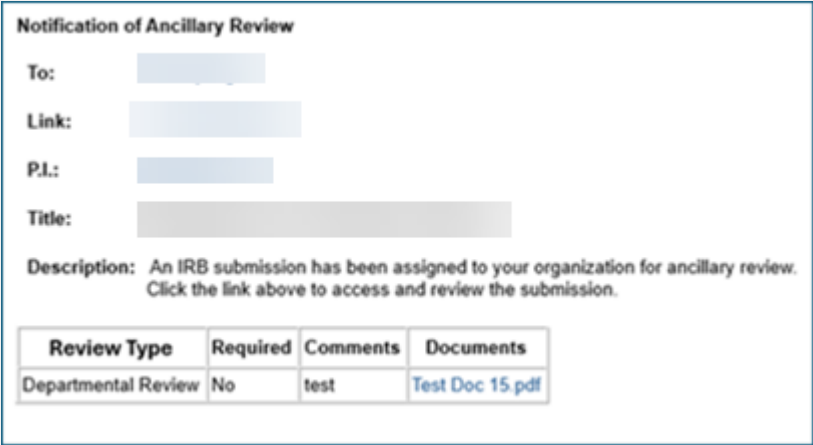


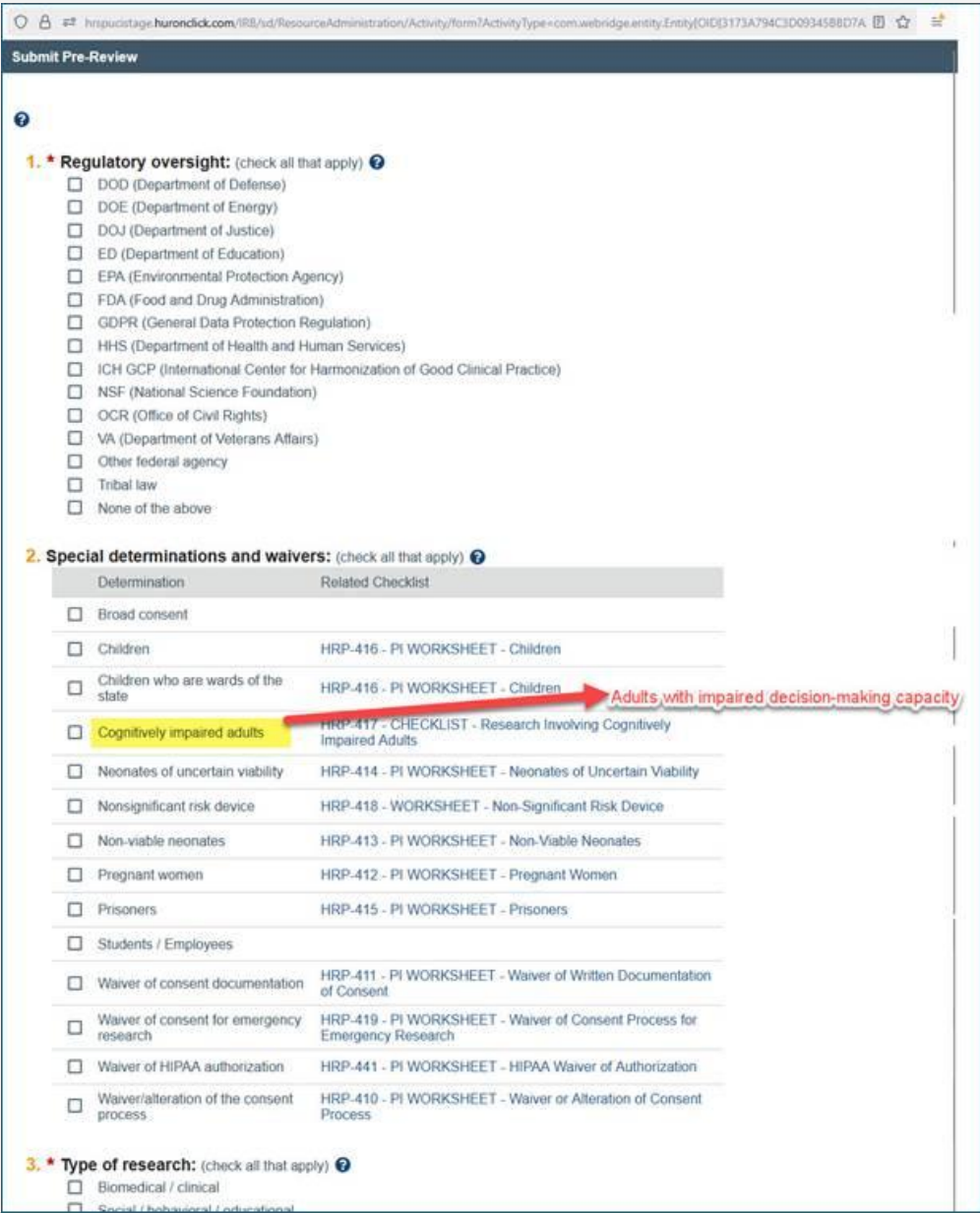
ZOT IRB System Release Notes

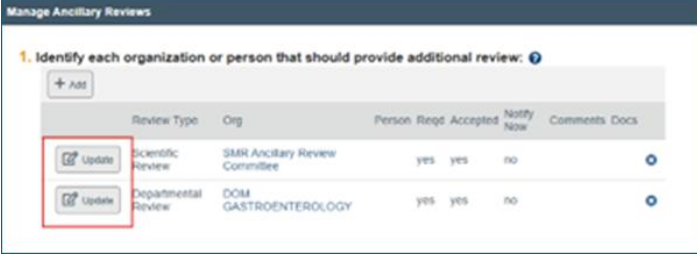
System: ZOT IRB | Release Date: 05/11/2026 | Prepared by: Electronic Research Administration

IRB (For Researchers)										
Enhancements										
#	Summary	Description								
1	Notifications: Ancillary Review emails now include Review Type, Required, Comments, and Supporting Documents.	<p>Example:</p>  <table border="1"> <thead> <tr> <th>Review Type</th> <th>Required</th> <th>Comments</th> <th>Documents</th> </tr> </thead> <tbody> <tr> <td>Departmental Review</td> <td>No</td> <td>test</td> <td>Test Doc 15.pdf</td> </tr> </tbody> </table>	Review Type	Required	Comments	Documents	Departmental Review	No	test	Test Doc 15.pdf
Review Type	Required	Comments	Documents							
Departmental Review	No	test	Test Doc 15.pdf							
2	If Continuing Review reminders miss a scheduled run, they are sent on the next run (first night may send duplicates).	Previously, if continuing review reminders did not run on a given day, those notifications would not be sent the following day. The system has been updated so that <u>if a CR reminder is missed, it will automatically be triggered on the next scheduled run</u> , ensuring no notifications are lost. Please note that on the first night following this update, some duplicate reminders may be sent, as the system is unable to determine whether past reminders were already delivered for previously created studies.								
3	Study team members (not just PI/Proxy) can Manage and Submit Ancillary Reviews.	The permissions for the Manage Ancillary Reviews activity have been updated to allow any study team member on a submission to perform this action, in addition to the Principal Investigator (PI) and Proxy. This removes the previous restriction that limited this activity to only the PI or Proxy, making it easier for study teams to manage ancillary reviews without unnecessary steps.								
Bug Fixes										
1	Hide "Do you accept the proposed submission" field from PI/Study Team Members for Manage Ancillary Reviews update button.	Previously, the "Do you accept the proposed submission" field was visible to the Principal Investigator (PI) and Study Team Members (STM) in the Manage Ancillary Reviews – Update activity. This field is no longer visible to PI and STM, ensuring that only the appropriate reviewers can perform the approval action. Additionally, the Delete button in Manage Ancillary Reviews now follows conditional visibility rules: it remains visible when a submission is in the Pre-Submission state and is hidden for PI and STM in all other submission states. These changes apply only to user interface visibility and do not impact workflow behavior or backend processing.								

IRB (For Researchers & IRB Staff)

Enhancements

#	Summary	Description																														
1	Terminology updated to 'Adults with impaired decision-making capacity.'	<p>The determination name in the Special Determinations and Waivers section has been updated from "Cognitively impaired adults" to "Adults with impaired decision-making capacity" to reflect updated regulatory language and toolkit documents.</p>  <p>The screenshot shows a web browser window with the URL https://hispucistage.huronclick.com/IRB/rd/ResourceAdministration/Activity/form?ActivityType=com.webbridge.entity.Entity(CID)3173A794C3D0934588D7A. The page title is "Submit Pre-Review".</p> <p>Section 1: Regulatory oversight: (check all that apply) ?</p> <ul style="list-style-type: none"> <input type="checkbox"/> DOD (Department of Defense) <input type="checkbox"/> DOE (Department of Energy) <input type="checkbox"/> DOJ (Department of Justice) <input type="checkbox"/> ED (Department of Education) <input type="checkbox"/> EPA (Environmental Protection Agency) <input type="checkbox"/> FDA (Food and Drug Administration) <input type="checkbox"/> GDPR (General Data Protection Regulation) <input type="checkbox"/> HHS (Department of Health and Human Services) <input type="checkbox"/> ICH GCP (International Center for Harmonization of Good Clinical Practice) <input type="checkbox"/> NSF (National Science Foundation) <input type="checkbox"/> OCR (Office of Civil Rights) <input type="checkbox"/> VA (Department of Veterans Affairs) <input type="checkbox"/> Other federal agency <input type="checkbox"/> Tribal law <input type="checkbox"/> None of the above <p>Section 2: Special determinations and waivers: (check all that apply) ?</p> <table border="1"> <thead> <tr> <th>Determination</th> <th>Related Checklist</th> </tr> </thead> <tbody> <tr> <td><input type="checkbox"/> Broad consent</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Children</td> <td>HRP-416 - PI WORKSHEET - Children</td> </tr> <tr> <td><input type="checkbox"/> Children who are wards of the state</td> <td>HRP-416 - PI WORKSHEET - Children</td> </tr> <tr> <td><input type="checkbox"/> Cognitively impaired adults</td> <td>HRP-417 - CHECKLIST - Research Involving Cognitively Impaired Adults</td> </tr> <tr> <td><input type="checkbox"/> Neonates of uncertain viability</td> <td>HRP-414 - PI WORKSHEET - Neonates of Uncertain Viability</td> </tr> <tr> <td><input type="checkbox"/> Nonsignificant risk device</td> <td>HRP-418 - WORKSHEET - Non-Significant Risk Device</td> </tr> <tr> <td><input type="checkbox"/> Non-viable neonates</td> <td>HRP-413 - PI WORKSHEET - Non-Viable Neonates</td> </tr> <tr> <td><input type="checkbox"/> Pregnant women</td> <td>HRP-412 - PI WORKSHEET - Pregnant Women</td> </tr> <tr> <td><input type="checkbox"/> Prisoners</td> <td>HRP-415 - PI WORKSHEET - Prisoners</td> </tr> <tr> <td><input type="checkbox"/> Students / Employees</td> <td></td> </tr> <tr> <td><input type="checkbox"/> Waiver of consent documentation</td> <td>HRP-411 - PI WORKSHEET - Waiver of Written Documentation of Consent</td> </tr> <tr> <td><input type="checkbox"/> Waiver of consent for emergency research</td> <td>HRP-419 - PI WORKSHEET - Waiver of Consent Process for Emergency Research</td> </tr> <tr> <td><input type="checkbox"/> Waiver of HIPAA authorization</td> <td>HRP-441 - PI WORKSHEET - HIPAA Waiver of Authorization</td> </tr> <tr> <td><input type="checkbox"/> Waiver/alteration of the consent process</td> <td>HRP-410 - PI WORKSHEET - Waiver or Alteration of Consent Process</td> </tr> </tbody> </table> <p>Section 3: Type of research: (check all that apply) ?</p> <ul style="list-style-type: none"> <input type="checkbox"/> Biomedical / clinical <input type="checkbox"/> Social / behavioral / educational 	Determination	Related Checklist	<input type="checkbox"/> Broad consent		<input type="checkbox"/> Children	HRP-416 - PI WORKSHEET - Children	<input type="checkbox"/> Children who are wards of the state	HRP-416 - PI WORKSHEET - Children	<input type="checkbox"/> Cognitively impaired adults	HRP-417 - CHECKLIST - Research Involving Cognitively Impaired Adults	<input type="checkbox"/> Neonates of uncertain viability	HRP-414 - PI WORKSHEET - Neonates of Uncertain Viability	<input type="checkbox"/> Nonsignificant risk device	HRP-418 - WORKSHEET - Non-Significant Risk Device	<input type="checkbox"/> Non-viable neonates	HRP-413 - PI WORKSHEET - Non-Viable Neonates	<input type="checkbox"/> Pregnant women	HRP-412 - PI WORKSHEET - Pregnant Women	<input type="checkbox"/> Prisoners	HRP-415 - PI WORKSHEET - Prisoners	<input type="checkbox"/> Students / Employees		<input type="checkbox"/> Waiver of consent documentation	HRP-411 - PI WORKSHEET - Waiver of Written Documentation of Consent	<input type="checkbox"/> Waiver of consent for emergency research	HRP-419 - PI WORKSHEET - Waiver of Consent Process for Emergency Research	<input type="checkbox"/> Waiver of HIPAA authorization	HRP-441 - PI WORKSHEET - HIPAA Waiver of Authorization	<input type="checkbox"/> Waiver/alteration of the consent process	HRP-410 - PI WORKSHEET - Waiver or Alteration of Consent Process
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2	Re-enabled 'Update' on Manage Ancillary Reviews.	The Update button in the Manage Ancillary Reviews activity was previously hidden, preventing users from making necessary updates. The Update button has now been re-enabled for all users with access, allowing ancillary reviews to be updated as needed.																														

		
<p>3 Added 'Send Notification Now' to alert ancillary reviewers during Pre-Submission (prevents duplicate on submission).</p>	<p>Known Issue: There is currently a known bug where updated Comments are not displaying in the Manage Ancillary Reviews screen (however, they do appear correctly in the Reviews tab). Huron has been notified and a fix is planned for a future update.</p>	<p>Previously, when ancillary reviewers were added during the Pre-Submission state, notifications were only sent at the time of submission. A new "Send Notification Now" field is now available in the Manage Ancillary Reviews activity. When selected, <u>notifications are sent immediately after ancillary reviewers are added in Pre-Submission</u>. To avoid duplicates, those reviewers will not receive the same notification again at the time of submission.</p>
<p>4 Removed "Evaluation instruments and surveys" from the help text on the Local Site Documents Smartform page, Recruitment Materials section.</p>		<p>The help text entry "Evaluation instruments and surveys" has been removed from the Recruitment Materials section of the Local Site Documents Smartform.</p>
<p>Bug Fixes</p>		
<p>1 External IRB data clears when toggled from Yes to No (with migration).</p>		<p>Previously, when a study was set to external and information was entered and saved under the External IRB SmartForm, changing the external setting from "Yes" to "No" on the Basic Study Information SmartForm would not clear the previously entered data. This has been corrected — changing the external setting to "No" will now clear the data previously entered in the External IRB and Basic Site Information SmartForms. A data migration has also been performed to clear existing External IRB SmartForm and Basic Site Information data from affected records.</p>
<p>2 Accessibility: Workflow map descriptions and key action links (e.g., 'Create New Study', 'Report New Information') now have descriptive labels for screen readers.</p>		<ul style="list-style-type: none"> • When hovering over the workflow map on submission workspaces, the corresponding description of the workflow map state will now be read aloud by screen readers. • When hovering over key action buttons such as "Create New Study" and "Report New Information," the corresponding button names will now be read aloud by screen readers.
<p>3 Meeting Minutes Template shows notes under the correct protocol when multiple</p>		<p>Previously, when generating IRB Meeting Minutes, notes entered for one protocol were incorrectly displayed under another protocol when a meeting included three or more studies, causing note data to shift between protocols in the generated document. The Meeting Minutes Template has been corrected to display notes and review information</p>

	studies are on an agenda.	under their respective protocols, ensuring accurate and clear meeting minutes.
4	Multi-Site Study Guide: Steps updated for "Update Study Details."	The topic "Update Study Details for a Multi-Site External Study" under sIRB Researchers has been updated to reflect the exact procedure for updating study details.
5	RNI Compare now captures and displays changes made while the RNI is in the Action Required state.	The Compare feature for RNIs has been fixed to correctly capture and display changes made while the RNI is in the Action Required state.

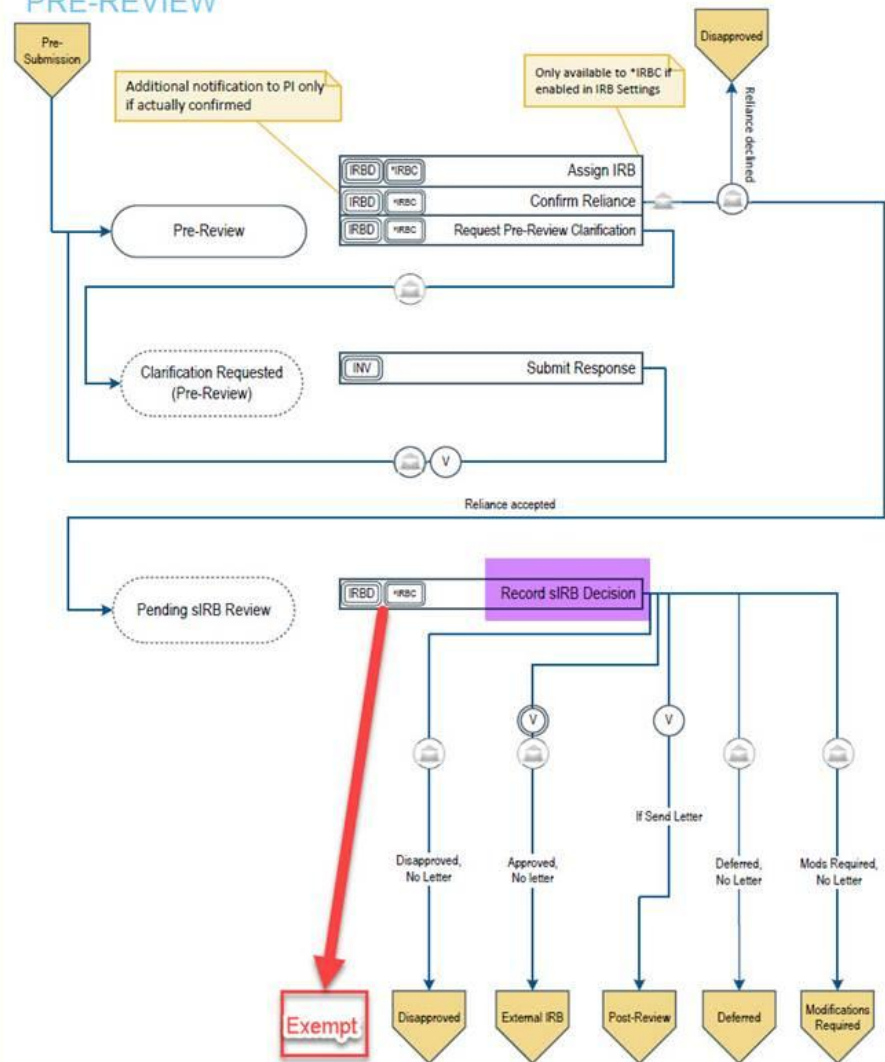
IRB (For IRB Staff)

Enhancements

#	Summary	Description
1	Added 'Exempt' as a determination on Record sIRB Decision for External Single Site submissions; Selecting Exempt moves the study to Approved.	<ul style="list-style-type: none"> • A new determination option titled "Exempt" is now available in the Record sIRB Decision and Edit sIRB Decision activity. When "Exempt" is selected as the determination and the review is submitted, the study will automatically transition to the Approved state. • This "Exempt" determination option is only available for External Single Site Studies and does not apply to Site Modifications or IRB Site submissions. • This applies only to the "Record sIRB Decision" and "Edit sIRB Decision" activities • No notifications are triggered by this action.

EXTERNAL STUDY

PRE-REVIEW



2 Expedited Review: added 'IRB chair concurrence' category with sub-options for non-emergency individual patient drug expanded access and non-emergency individual/small group compassionate use of a device.

- In the Expedited Review process, under the 'Indicate the Categories' section, a new category titled 'IRB chair concurrence' is now available. When this option is selected, two additional sub-checkboxes will appear: 'Non-emergency individual patient drug expanded access' and 'Non-emergency individual/small group compassionate use of a device.' If the 'IRB chair concurrence' category is deselected, these two sub-checkboxes will be automatically hidden.
- The following descriptions have been added for the newly available IRB Expedited Categories:
 - IRB chair concurrence: IRB chair concurs with non-emergency use.
 - Non-emergency individual patient drug expanded access: Chair concurs with non-emergency individual patient drug expanded access.
 - Non-emergency individual/small group compassionate use of a device: Chair concurs with non-emergency individual/small group compassionate use of a device.

Submit Designated Review

1. * Determination:

Name	Related Worksheet
<input checked="" type="radio"/> Approved	HRP-314 - WORKSHEET - Criteria for Approval
<input type="radio"/> Modifications Required to Secure "Approved"	HRP-314 - WORKSHEET - Criteria for Approval
<input type="radio"/> Not Human Research	HRP-310 - WORKSHEET - Human Research Determination
<input type="radio"/> Modifications Required to Secure "Not Human Research"	HRP-310 - WORKSHEET - Human Research Determination
<input type="radio"/> Human Research, Not Engaged	HRP-311 - WORKSHEET - Engagement Determination
<input type="radio"/> Modifications Required to Secure "Human Research, Not Engaged"	HRP-311 - WORKSHEET - Engagement Determination

[Clear](#)

2. * Risk level:

Greater than minimal risk

No greater than minimal risk

N/A

[Clear](#)

3. Pediatric risk levels:

21 CFR §50.51/45 CFR §46.404: Not involving greater than minimal risk

21 CFR §50.52/45 CFR §46.405: Greater than minimal risk; prospect of direct benefit for individual subjects

21 CFR §50.53/45 CFR §46.406: Greater than minimal risk; no prospect of direct benefit but likely to yield generalizable knowledge

21 CFR §50.54/45 CFR §46.407: Not otherwise approvable

Complete and attach the following checklist: HRP-416 - PI WORKSHEET - Children

4. * Review level:

Name	Related Worksheet
<input type="radio"/> Exempt	HRP-312 - WORKSHEET - Exemption Determination
<input checked="" type="radio"/> Expedited	HRP-313 - WORKSHEET - Eligibility for Review Using the Expedited Procedure

[Clear](#)

5. * Indicate the categories: (see HRP-313 for full regulatory criteria, check all that apply)

- (1)(a) Drug studies
- (1)(b) Device studies
- (2)(a) Blood samples from healthy, non-pregnant adults
- (2)(b) Blood samples from others
- (3) Noninvasive biological specimens
- (4) Noninvasive procedures
- (5) Data, documents, records, or specimens
- (6) Voice, video, digital, or image recordings
- (7)(a) Behavioral research
- (7)(b) Social science methods
- (8)(a) Long-term follow-up
- (8)(b) No subjects enrolled
- (8)(c) Data analysis
- (9) Convened IRB determined minimal risk
- (mm) Minor modification
- Other

6. Dates:

* Approval date:

Effective date:

Last day of approval period:

4. * Indicate the categories: (see HRP-313 for full regulatory criteria, check all that apply)

- (1)(a) Drug studies
- (1)(b) Device studies
- (2)(a) Blood samples from healthy, non-pregnant adults
- (2)(b) Blood samples from others
- (3) Noninvasive biological specimens
- (4) Noninvasive procedures
- (5) Data, documents, records, or specimens
- (6) Voice, video, digital, or image recordings
- (7)(a) Behavioral research
- (7)(b) Social science methods
- (8)(a) Long-term follow-up
- (8)(b) No subjects enrolled
- (8)(c) Data analysis
- (9) Convened IRB determined minimal risk
- IRB chair concurrence
 - Non-emergency individual patient drug expanded access
 - Non-emergency individual/group compassionate use of a device
- Other

3 Continuing Review controls: CR fields on Review Required Modifications are read-only.

In the "Review Required Modifications" activity, the "Is continuing review required?", "Rationale for continuing review requirement," and "Last day of approval period" fields are now set to read-only to prevent edits, as the determination is made by the full board. The fields remain visible but cannot be edited.

4 Auto-set CR required to 'No' when determination is Not Human Research or Human Research, Not Engaged.

For Study, Modification, and Continuing Review submissions: when the determination is set to "Not Human Research" or "Human Research, Not Engaged" and no input has been provided for the "Is continuing review required?" question, the system will now automatically populate that field with "No." If any other determination is selected, the value for "Is continuing review required?" will be reset.

5 Hide CR question when determination is Deferred (legacy values cleared via migration).

When executing the "Submit Committee Review" activity, the "Is continuing review required?" question will now be hidden upon selecting "Deferred" as the determination value. This applies to Study, Modification, and Continuing Review submissions. Additionally, a data

migration has been performed to clear the following values from existing records where the determination is set to Deferred:

- Is Continuing Review Required
- Rationale for continuing review requirement
- Last day of approval period

Submit Committee Review

1. * **Determination:**

Name	Related Worksheet
<input type="radio"/> Approved	HRP-314 - WORKSHEET - Criteria for Approval
<input type="radio"/> Modifications Required to Secure "Approved"	HRP-314 - WORKSHEET - Criteria for Approval
<input type="radio"/> Not Human Research	HRP-310 - WORKSHEET - Human Research Determination
<input type="radio"/> Modifications Required to Secure "Not Human Research"	HRP-310 - WORKSHEET - Human Research Determination
<input type="radio"/> Human Research, Not Engaged	HRP-311 - WORKSHEET - Engagement Determination
<input type="radio"/> Modifications Required to Secure "Human Research, Not Engaged"	HRP-311 - WORKSHEET - Engagement Determination
<input checked="" type="radio"/> Deferred	
<input type="radio"/> Disapproved	

2. * **Risk level:**

Greater than minimal risk

No greater than minimal risk

N/A

3. * **Is continuing review required?**

Yes No

4. **Rationale for continuing review requirement:**

Reviewed at Subcommittee

For old data: Clear the below values if the determination selection is Deferred:

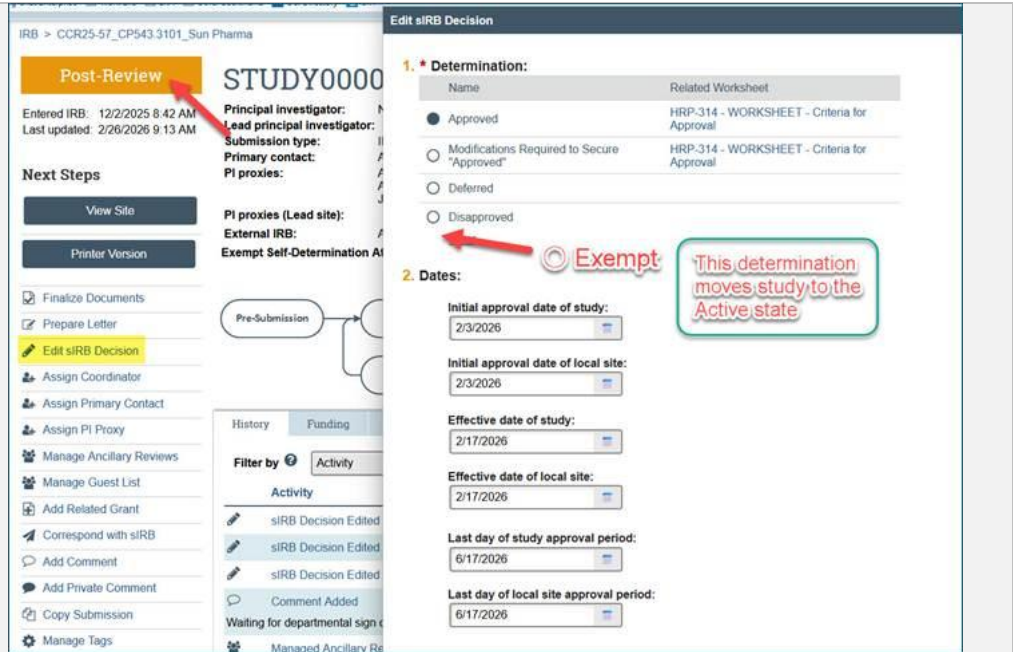
- Is Continuing Review Required
- Rationale for continuing review requirement
- Last day of approval period

6 Reporting: Device Usage and Drug Usage reports now have search boxes (Drug report supports Generic vs. Brand filter).

- A new search text box has been added to the "Device Usage" report, allowing users to search for studies by entering partial device names or keywords. This makes it easier to locate specific devices in the report, similar to the Device Smartform search functionality.
- A search box has also been added to the "Drug Usage" report for searching drug names, similar to the Drug Smartform. A new dropdown filter allows users to choose between searching by Generic Name or Brand Name, making drug searches more efficient.

7 Multi-Site Studies: Added 'Exempt' determination to Record/Edit sIRB Decision for multi-site initial external submissions; selecting Exempt moves the study to Active (not

- A new determination option titled "Exempt" is now available in the Record sIRB Decision and Edit sIRB Decision activities for multi-site studies. When "Exempt" is selected and the review is submitted, the study will move to the Active state. This option is only available for initial External Submissions and does not apply to Site Modifications.
- No notifications are triggered for this activity.

<p>applicable to Site Modifications).</p>	
<p>8 Ability to administratively close studies in Not Human Research or Human Research, Not Engaged.</p>	<ul style="list-style-type: none"> • It is now possible to administratively close studies that are in the "Human Research, Not Engaged" or "Not Human Research" state. • The "Close Study (Admin)" activity is available for studies in the following states: Approved, Not Human Research, Human Research, Not Engaged, Suspended, Lapsed, and External IRB. • Users with the IRB Director or IRB Coordinator role will be able to execute this activity and see this activity in all applicable scenarios. Additionally, the "Close Study (Admin)" button will also be available to the coordinator assigned to the study.
<p>9 AAHRPP reporting updated to count external single- and multi-site studies with Exempt vs. non-Exempt determinations.</p>	<p>The AAHRPP report has been updated with the following changes:</p> <ul style="list-style-type: none"> • Point #26: Now shows the number of external single-site and multi-site studies with an Exempt determination for the most recent year. • Point #28: Now shows the number of external single-site and multi-site studies with a determination other than Exempt.
<p>10 IRB Staff Guide updates</p>	<ul style="list-style-type: none"> • A new topic, "Close a Study (Admin)," has been added to illustrate the steps for administratively closing a study in the Not Human Research or Human Research, Not Engaged state. • The topic "Manage Ancillary Reviews" has been updated to clarify that this activity can be executed by study team members and that ancillary reviews can be sent in the Pre-Submission state. • The topic "AAHRPP Report Details" has been updated to include multi-site studies for external submissions with an exempt determination.
<p>11 Bulk Import now sets Performance Metrics Review Type correctly (null for external studies), with migration to correct prior records.</p>	<ul style="list-style-type: none"> • You can view this in the Advanced report, and the report name is "IRB Turnaround Times". • An issue has been resolved where the Performance Metrics Review Type for bulk-imported external studies was incorrectly displaying "Committee." This value is now correctly set to null for newly imported records. A data migration has also been applied

		to update existing records where "Committee" was previously set incorrectly.
Bug Fixes		
1	IRB Coordinator assigned to a Site Modification can edit attached Site Mod documents.	The IRB Coordinator assigned to a Site Modification can now edit attached documents on the Site Modification SmartForms, even if they are not assigned to the parent study.
2	'Expedited Submissions Approved in the Last 45 Days' report now includes only submissions whose latest review is designated Expedited.	Follow-on submissions and their parent studies were incorrectly appearing in the "Expedited Submissions Approved in the Last 45 Days" report. This has been resolved by updating the report logic to include only submissions where the latest review is designated as expedited, ensuring the report reflects accurate and relevant data.
3	Restricted 'Submit RNI Pre-Review' activity visibility to IRB staff only (no longer visible to PIs/study team who are also Committee Members).	Previously, Principal Investigators and study team members who also held an IRB Committee Member role could access the Submit RNI Pre-Review activity, allowing unintended visibility of internal comments and attachments. This has been corrected so that only designated IRB staff can access this activity.
4	Expedited Submissions Approved in Last 45 Days report incorrectly included studies whose initial review was Committee Review.	The logic for the "Expedited Submissions Approved in Last 45 Days" report has been updated to address an issue where studies were incorrectly included when a follow-on submission using Committee Review was approved after an expedited review had been submitted on the initial submission. The report now evaluates the latest review activity at the submission level and includes only those submissions where the most recent review is an expedited designated review, preventing incorrect inclusion due to review history being carried forward across submissions.