

Huron IRB 10.5 Release Overview



Agenda

1. Huron IRB 10.5 Overview
2. RNI Improvements
3. Updated AAHRPP Reporting
4. Study Discard
5. Study Tagging
6. Study Update Setting
7. PI Proxy Consistency



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Huron IRB 10.5 Overview



IRB 10.5 Upgrade Pre-requisites

- Huron Portal 10.0.3 or later
- Huron Foundation Site 10.0.0 (for new installs)
- Huron Global Common 10.5.0
- Huron IRB 10.1.0 (for upgrades)

IRB 10.5 Release

Primary Focus

RNI Improvements

- Enable IRB Data Manager to add, edit, and disable categories
- Incorporating Ancillary Review functionality
- Related submission PI or PI Proxy ability to Edit and Submit
- New Manage Editors activity, providing additional access to take action on RNIs
- Action Required is now an editable state
- New Standard Report: New Information Reports by Category

Updated AAHRPP Reporting

- New AAHRPP Report template to align with AAHRPP's updated report format
- Reporting now includes calculation of over 20 values not previously available

Study Discard

- Allow IRB Staff to discard submissions in various states
- Allow sIRB sites to be discarded in various states

Study Tagging

- New activity titled Manage Tags
- IRB staff ability to manage tags on submissions
- New Standard Report: IRB Submissions with Tags

IRB 10.5 Release - continued

Primary Focus

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- | | |
|----------------------|--|
| Study Update Setting | • New setting to determine if the PI should be able to execute the Finalize Study Update activity for External Studies |
|----------------------|--|
-
- | | |
|----------------------|---|
| PI Proxy Consistency | • PI Proxy allowed to submit Continuing Reviews on behalf of the PI |
|----------------------|---|
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RNI Improvements



RNI Improvements

Objectives

1

Ability to add, edit, and disable the RNI categories.

3

Related PI or PI Proxy ability to Edit and Submit

2

Manage & submit Ancillary Reviews

4

Action Required as an editable state

RNI Improvements (continued)

Objectives

5

New Manage Editors activity

7

New Standard Report: New Information Reports by Category

6

New Final Page

RNI Improvements

Ability to Add, Edit & Disable Categories

- **RNI Categories tab added to IRB Settings workspace. IRB Data Manager has access to add, edit and disable RNI categories.**
- Names of delivered categories will remain as read-only. Descriptions of delivered categories are editable and can be disabled.
- Form to add or edit RNI Category
- Display on RNI Smart Form Page

Add Reportable New Information Category

1. * **Name:**

2. **Description:**

This is the description of the new category.

3. **Display order:**

4. * **Active?**

True False [Clear](#)

* Required

OK

OK and Add Another

Cancel

New RNI Category

This is the description of the new category.

RNI Improvements

Ancillary Review Functionality

- Added Manage Ancillary Reviews activity to all RNI states except for Discarded
- Expanded the Submit Ancillary Review activity
- Added workflow stoppage for outstanding required ancillary reviews
- Users added as ancillary reviewers are now granted read access to the submissions
- Added Ancillary Reviews to the workspace Reviews tab
- Submit RNI activity sends notification to ancillary reviewers

Pre-Submission

Last updated: 9/23/2022 12:32 PM

Next Steps

Edit RNI

Printer Version

Submit RNI

Manage Ancillary Reviews

Manage Editors

Add Related Submission

Add Comment

Copy Submission

Discard

Manage Tags

RNI Improvements

Related PI/PI Proxy Edit and Submit

Expanded Ability to Edit RNIs in Action Required state

- Updated RNI security to allow the related submissions' PI and proxies to edit
- Submit RNI activity is now accessible to related submissions' PI and PI proxies
- Expanded ability to edit RNIs in Action Required state

Next Steps

Edit RNI

Printer Version

Submit RNI

+ Add Related Submission

Add Comment

Discard

RNI Improvements

New Manage Editors Activity

- Added a new activity called Manage Editors
- Activity is available to the IRB Coordinator, IRB Director and RNI Creator in all states
- Selected additional editors can edit and submit an RNI in states where edit/submit is available.
- Once the editor has submitted the RNI or submitted a response, the RNI will be read-only

Manage Editors

i The following people can edit the details of this new information without being on the editors list and Reported by can also submit:

Reported by: [?](#)
System Administrator

Related studies: [?](#)

ID	Investigator	PI Proxies
STUDY00000024	Rebecca Simms (pi)	

1. Additional people who can edit and submit the new information: [?](#)

...

First Name	Last Name	Employer	Title
There are no items to display			


RNI Improvements

New Final Page

Final Page

You have reached the end of the IRB new information form. Read the next steps carefully:


1. Click **Finish** to exit the form.
2. **Important!** To send the new information for review, click **Submit RNI** on the next page.

 Exit Save Finish

RNI Improvements

New Standard Report: New Information Reports by Category

New Information Reports by Category



[? Help](#)
Filter by 

ID




[+ Add Filter](#)
[Actions](#)

[X Clear All](#)

ID	Name	Project Status	Category	Submitter First Name	Submitter Last Name	IRB	Date Entered IRB	Related Submissions	Investigator
RNI00000001	Protocol deviation	Complete	Risk	Rebecca	Simms (pi)	Exchange	8/28/2022 6:08 PM	STUDY00000003	Rebecca Simms (pi) 
RNI00000002	_IRBSubmission - 8/11/2022 7:28:38 PM	Complete	Incarceration	System	Administrator	Exchange	8/11/2022 12:35 PM	STUDY00000003	Rebecca Simms (pi) 



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Updated AAHRPP Reporting



Updated AAHRPP Reporting

New AAHRPP Report Template



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of Human Research Protection Programs, Inc.®

[Generate AAHRPP Report](#)

Updated AAHRPP Reporting

New AAHRPP Report Template

Name of calculated field	Explanation
Number of active protocols	
Number of protocols reviewed by a convened IRB/EC	Total number of initial studies currently in Approved, Lapsed, or Suspended state where Date Approved is within the last year and where the review type is Committee.
Number of protocols reviewed by an Expedited Review	Total number of initial studies currently in Approved, Lapsed, or Suspended state where Date Approved is within the last year and where the review type is Expedited.
Research activities determined to be Exempt in the past 12 months	Total number of initial studies currently in Approved, Lapsed, or Suspended state where Date Approved is within the last year and where the review type is Exempt.
Protocols reviewed by an external IRB	Total number of initial studies and initial sites currently in Active, External IRB, or Suspended state where Date Approved is within the last year and where an external IRB was involved. The total excludes submissions that do not include an approval date, which is optional for external IRB submissions.
Total number of active protocols	Total number of protocols counted in the previous calculations for those reviewed by a convened IRB/EC, by Expedited Review, determined to be Exempt, and reviewed by an external IRB.
How many research activities were reviewed by the Limited Review Procedure in the past 12 months?	Total number of initial studies currently in Approved, Lapsed, or Suspended state where Date Approved is within the last year and where limited IRB review is indicated by one of the selected Exempt categories—any of these categories: (2)(iii), (3)(i)(C), (7), and (8). These studies are a subset of the Exempt studies counted above.

- See the [AAHRPP Report Details](#) topic in the *IRB Staff Guide* or [Solution Central](#)

Updated AAHRPP Reporting

New AAHRPP Report Template

Median review and approval times (days)	
For new protocols reviewed in the most recent 12 months by the convened IRB/EC , what is the median number of calendar days from complete submission to...	Review: Median elapsed time in days from first transition into Pre-Review Completed state [†] to the scheduled date of the meeting to which the study was assigned when Submit Committee Review was performed on it for the first time (for all studies currently in Approved, Lapsed, or Suspended state and where the initial approval date is within the last year)
	Approval: Median elapsed time in days from first transition into Pre-Review Completed state [†] to initial study approval or initial effective date, whichever is later (for all studies currently in Approved, Lapsed, or Suspended state and where the initial approval date is within the last year)
For new protocols reviewed in the most recent 12 months by the expedited procedure , what is the median number of calendar days from complete submission to...	Review: Median elapsed time in days from first transition into Pre-Review Completed state [†] to Assign Designated Reviewer activity being performed for the first time for the study (for all studies currently in Approved, Lapsed, or Suspended state and where the initial approval date is within the last year)
	Approval: Median elapsed time in days from Assign Designated Reviewer activity being performed for the first time for the study to initial study approval or initial effective date, whichever is later (for all studies currently in Approved, Lapsed, or Suspended state and where the initial approval date is within the last year)
For new protocols reviewed in the most recent 12 months and given an exempt determination, what is the median number of calendar days from complete submission to...	Review: Median elapsed time in days from first transition into Pre-Review Completed state [†] to Assign Designated Reviewer activity being performed for the first time for the study (for all studies currently in Approved, Lapsed, or Suspended state and where the initial approval date is within the last year)
	Approval: Median elapsed time in days from Assign Designated Reviewer activity being performed for the first time for the study to initial study approval or initial effective date, whichever is later (for all studies currently in Approved, Lapsed, or Suspended state and where the initial approval date is within the last year)

Updated AAHRPP Reporting

New AAHRPP Report Template

Disapprovals, non-compliance, and unanticipated problems	
Number of protocols disapproved by the IRB/EC in the past 12 months	Total number of initial studies currently in Disapproved state that entered Disapproved state within the last year
Number of new cases of alleged non-compliance investigated in the most recent 12 months	Number of RNI submissions that reached the Acknowledged or Completed state in the last 12 months with a determination ^S of "Allegation of non-compliance with no basis in fact"
Number of determinations of serious non-compliance in the most recent 12 months	Number of RNI submissions that reached the Acknowledged or Completed state in the last 12 months with a determination ^S of "Serious non-compliance"
Number of determinations of continuing non-compliance in the most recent 12 months	Number of RNI submissions that reached the Acknowledged or Completed state in the last 12 months with a determination ^S of "Continuing non-compliance"
Number of determinations of unanticipated problems involving risks to participants or others in the most recent 12 months	Number of RNI submissions that reached the Acknowledged or Completed state in the last 12 months with a determination ^S of "Unanticipated problem involving risks to subjects or others"



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Study Discard



Submission Discard

Administrative Ability to Discard

IRBC or IRBD ability to discard submissions in the following states:

Clarifications Requested (Committee Review)

Clarifications Requested (Designated Review)

Clarifications Requested (Pre-Review)

Modifications Required

Disapproved

Deferred

Awaiting Site Materials (sIRB site)

Pending sIRB Review (pSite)

Updating Study

Pre-Submission

Pre-Review

Committee Review

Invitation Pending

Pre-Review Completed

Non-Committee Review



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Study Tagging



Study Tagging

New Settings Tab & Ability to Add Tags

IRB Settings

Agenda & Minutes Templates		Ancillary Reviews		Attachment Categories		IRB Tags		...	
+									
Filter by [?]		Name	▼	Enter text to search			Q	⚙	
+ Add Filter	✕ Clear All								
Name		Active							
✎	Minimal Risk Determination	False							
✎	Phase II	True							
✎	Phase IV	True							
✎	Coronavirus Disease (COVID-19)	True							
✎	Cancer Research	True							
✎	Fast Track	True							
✎	Future Use	False							
✎	NCI	True							

Add IRB Tag

1. * IRB tag: [?]

2. * Active?

True False [Clear](#)

Study Tagging

New Activity “Manage Tags”

Next Steps

View Study

Printer Version

Send Letter

Prepare Letter

Submit Designated Review

Assign Coordinator

Assign Primary Contact

Assign PI Proxy

Manage Ancillary Reviews

Manage Guest List

Add Related Grant

Add Comment

Add Private Comment

Copy Submission

Close Study (Admin)

Manage Tags

Select One or More IRB Tags

Filter by Tag

Total Selected: 2 ◀◀ 1-10 of 10 ▶▶

Tag

- Cancer Research
- Coronavirus Disease (COVID-19)
- Fast Track
- NCI
- new tag for June Meeting
- Phase I
- Phase II

Total Selected: 2 ◀◀ 1-10 of 10 ▶▶

Manage Tags

1. Associate tags:



2. Comments:

- New IRB Activity, Manage Tags, that is accessible to Site Managers and IRB Staff with access to the IRB projects in all states.

Study Tagging

New Standard Report – Submissions with Tags

Submissions with Tags Report of submissions with tags

? Help

Filter by ID Enter text to search Actions ⚙️

🔍 + Add Filter ✖ Clear All

ID	Name	PI First Name	PI Last Name	Status	IRB Tags	🔍
RNI00000025	_IRBSubmission - 3/18/2022 7:49:31 PM	System	Administrator	Discarded	Tac Active	🔍
STUDY00000149	AB:MSS#41322#1	Joe	Bloggs (pi4)	Approved	Fast Track	🔍
STUDY00000294	AB:MSS#620#2	System	Administrator	Pre-Review Completed	Cancer Research NCI Phase I	🔍
STUDY00000014	An Open-Label Study of the Efficacy and Safety of Re-Treatments with Rituxi	Rebecca	Simms (pi)	Terminated	Test Tag1	🔍

Pop Out
Close

- New standard report Submissions with tags. Ability to filter by Name, PI First Name, PI Last Name, Status & IRB Tags

? Help

Filter by IRB Tags Enter text to search Actions ⚙️

🔍 + Add

IRB Tags

ID

Name

PI First Name

PI Last Name

Status

IRB Tags

PM

ID	Name	PI First Name	PI Last Name	Status	IRB Tags	🔍
RNI00000025	18/2022 7:49:31 PM	System	Administrator	Discarded	Tac Active	🔍



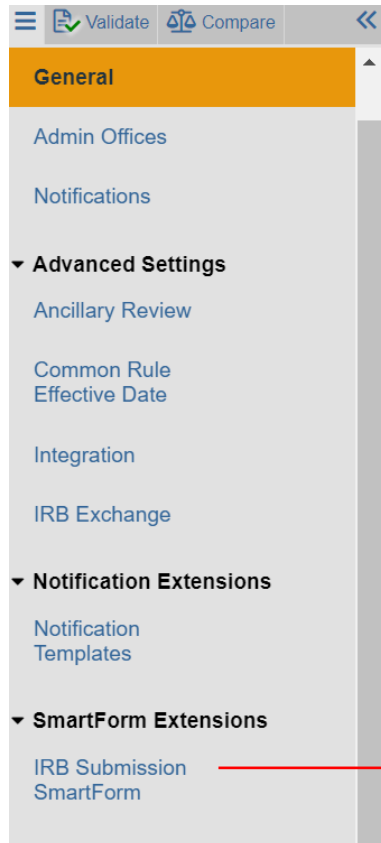
6

Study Update Setting



IRB Settings Update

New setting determines if PIs can execute Finalize Updates on External Single-Site Studies



General

1. **Automatically assign IRB coordinator to new modifications:**
 Yes No [Clear](#)
2. **Enable assigned coordinator to edit submissions on behalf of the study team:**
 Yes No [Clear](#)
3. **Enable PI proxies:**
 Yes No [Clear](#)
4. **Support review of VA research:**
 Yes No [Clear](#)
5. **Allow PIs to select the IRB office to review each new submission:**
 Yes No [Clear](#)
6. **Allow IRB coordinators to change the IRB office assigned to a submission:**
 Yes No [Clear](#)
7. **Allow PIs to finalize study updates of external single-site studies:**
 Yes No [Clear](#)

- New general setting allowing you to determine if the PI should be able to finalize updates for external single-site studies
- Selecting NO will remove the Finalize Updates activity from the PI workspace



7

PI Proxy Consistency



PI Proxy Consistency

PI Proxy Can Submit Continuing Review Data

Next Steps

View Study

Printer Version

Update Study Details


Report New Information

 Assign Primary Contact

 Manage Ancillary Reviews

 Report Continuing Review Data

 Add Comment

 Copy Submission

- The PI Proxy has ability to Report Continuing Review Data on sites and external studies.

For More Information

See Additional Documentation and Training

- **Documentation:**

- [Deploying IRB 10.5](#) in Solution Central
- [Using IRB 10.5](#) in Solution Central

- **Training:**

- Getting Started with Huron IRB v10.5 in the [Huron Learning Lab](#)
 - Will release by the end of December



Thank You

