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
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

**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
RNI
Improvements
RNI Improvements

Objectives

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

2. Manage & submit Ancillary Reviews

3. Related PI or PI Proxy ability to Edit and Submit

4. Action Required as an editable state
RNI Improvements (continued)

Objectives

5. New Manage Editors activity

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
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
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
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 Table]

1. Additional people who can edit and submit the new information:

<table>
<thead>
<tr>
<th>First Name</th>
<th>Last Name</th>
<th>Employer</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.
# RNI Improvements

## New Standard Report: New Information Reports by Category

### New Information Reports by Category

<table>
<thead>
<tr>
<th>ID</th>
<th>Name</th>
<th>Project Status</th>
<th>Category</th>
<th>Submitter First Name</th>
<th>Submitter Last Name</th>
<th>IRB</th>
<th>Date Entered IRB</th>
<th>Related Submissions</th>
<th>Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td>RNI00000001</td>
<td>Protocol deviation</td>
<td>Complete</td>
<td>Risk</td>
<td>Rebecca</td>
<td>Simms (pi)</td>
<td>Exchange</td>
<td>8/28/2022 6:08 PM</td>
<td>STUDY00000003</td>
<td>Rebecca Simms (pi)</td>
</tr>
<tr>
<td>RNI00000002</td>
<td>IRBSubmission</td>
<td>Complete</td>
<td>Incarceration</td>
<td>Administrator</td>
<td>Exchange</td>
<td>8/11/2022 12:36 PM</td>
<td>STUDY00000003</td>
<td>Rebecca Simms (pi)</td>
<td></td>
</tr>
</tbody>
</table>
Updated AAHRPP Reporting
Updated AAHRPP Reporting

New AAHRPP Report Template

Association for the Accreditation of Human Research Protection Programs, Inc.
# Updated AAHRPP Reporting

## New AAHRPP Report Template

<table>
<thead>
<tr>
<th>Name of calculated field</th>
<th>Explanation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of active protocols</strong></td>
<td></td>
</tr>
<tr>
<td>Number of protocols reviewed by a <strong>convened IRB/EC</strong></td>
<td>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.</td>
</tr>
<tr>
<td>Number of protocols reviewed by an <strong>Expedited Review</strong></td>
<td>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.</td>
</tr>
<tr>
<td>Research activities determined to be <strong>Exempt</strong> in the past 12 months</td>
<td>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.</td>
</tr>
<tr>
<td>Protocols reviewed by an <strong>external IRB</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>Total number of active protocols</strong></td>
<td>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.</td>
</tr>
<tr>
<td><strong>How many research activities were reviewed by the Limited Review Procedure in the past 12 months?</strong></td>
<td>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.</td>
</tr>
</tbody>
</table>

- See the AAHRPP Report Details topic in the **IRB Staff Guide** or Solution Central
# Updated AAHRPP Reporting

## New AAHRPP Report Template

<table>
<thead>
<tr>
<th>Median review and approval times (days)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>For new protocols reviewed in the most recent 12 months by the <em>convened</em> IRB/EC, what is the median number of calendar days from complete submission to...</td>
<td></td>
</tr>
<tr>
<td><strong>Review:</strong> Median elapsed time in days from first transition into Pre-Review Completed state(^1) 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)</td>
<td></td>
</tr>
<tr>
<td><strong>Approval:</strong> Median elapsed time in days from first transition into Pre-Review Completed state(^1) 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)</td>
<td></td>
</tr>
<tr>
<td>For new protocols reviewed in the most recent 12 months by the <em>expedited procedure</em>, what is the median number of calendar days from complete submission to...</td>
<td></td>
</tr>
<tr>
<td><strong>Review:</strong> Median elapsed time in days from first transition into Pre-Review Completed state(^1) 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)</td>
<td></td>
</tr>
<tr>
<td><strong>Approval:</strong> 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)</td>
<td></td>
</tr>
<tr>
<td>For new protocols reviewed in the most recent 12 months and given an <em>exempt</em> determination, what is the median number of calendar days from complete submission to...</td>
<td></td>
</tr>
<tr>
<td><strong>Review:</strong> Median elapsed time in days from first transition into Pre-Review Completed state(^1) 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)</td>
<td></td>
</tr>
<tr>
<td><strong>Approval:</strong> 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)</td>
<td></td>
</tr>
</tbody>
</table>
# Updated AAHRPP Reporting

## New AAHRPP Report Template

<table>
<thead>
<tr>
<th>Disapprovals, non-compliance, and unanticipated problems</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of protocols <strong>disapproved</strong> by the IRB/EC in the past 12 months</td>
<td>Total number of initial studies currently in Disapproved state that entered Disapproved state within the last year</td>
</tr>
<tr>
<td>Number of new cases of <strong>alleged non-compliance investigated</strong> in the most recent 12 months</td>
<td>Number of RNI submissions that reached the Acknowledged or Completed state in the last 12 months with a determination of &quot;Allegation of non-compliance with no basis in fact&quot;</td>
</tr>
<tr>
<td>Number of determinations of <strong>serious non-compliance</strong> in the most recent 12 months</td>
<td>Number of RNI submissions that reached the Acknowledged or Completed state in the last 12 months with a determination of &quot;Serious non-compliance&quot;</td>
</tr>
<tr>
<td>Number of determinations of <strong>continuing non-compliance</strong> in the most recent 12 months</td>
<td>Number of RNI submissions that reached the Acknowledged or Completed state in the last 12 months with a determination of &quot;Continuing non-compliance&quot;</td>
</tr>
<tr>
<td>Number of determinations of <strong>unanticipated problems involving risks to participants or others</strong> in the most recent 12 months</td>
<td>Number of RNI submissions that reached the Acknowledged or Completed state in the last 12 months with a determination of &quot;Unanticipated problem involving risks to subjects or others&quot;</td>
</tr>
</tbody>
</table>
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
5

Study Tagging
Study Tagging

New Settings Tab & Ability to Add Tags

IRB Settings

<table>
<thead>
<tr>
<th>Name</th>
<th>Active</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal Risk Determination</td>
<td>False</td>
</tr>
<tr>
<td>Phase II</td>
<td>True</td>
</tr>
<tr>
<td>Phase IV</td>
<td>True</td>
</tr>
<tr>
<td>Coronavirus Disease (COVID-19)</td>
<td>True</td>
</tr>
<tr>
<td>Cancer Research</td>
<td>True</td>
</tr>
<tr>
<td>Fast Track</td>
<td>True</td>
</tr>
<tr>
<td>Future Use</td>
<td>False</td>
</tr>
<tr>
<td>NCI</td>
<td>True</td>
</tr>
</tbody>
</table>

Add IRB Tag

1. * IRB tag:  

2. * Active?  
   - True  
   - False  
   Clear
Study Tagging
New Activity “Manage Tags”

- 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

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

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

- 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

- 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