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IRB7 System Updates & RNI

IRB Grand Rounds
Lois Pope Life Center, 7th Floor Auditorium
July 14, 2015

Presenter: Raquel Alfonso & Amanda Coltes

Authors: Raquel Alfonso, Amanda Coltes, Kanchan Sakhrani

Agenda

- Update Since IRB7 Implementation
  - System maintenance releases
- Evaluation of IRB 7 Configuration Change Requests
- Understanding Guidelines for IRB7 Customizations
- Upgrade Overview
  - Preview of New Features
  - High-level introduction to RNI workflow redesign
- Review of RNI current business process/guidelines

Update Since Implementation: December 2013

April 2014 → May 2014 → June 2014 → July 2014

Accomplishments

Enhancements:

- New UMiami Custom Inbox
- Documents Tab enhanced

System issues:

- Double water mark headers
- Modifications validation on missing data in required fields

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Update Since Implementation: December 2013

August 2014 → November 2014 → February 2015 → May 2015 → July 2015

Accomplishments

Enhancements:

- Meeting agenda fields no longer pulling null data
- Determination letter enhancements to reduce manual effort

System issues:

- Documents mismatched upon finalization
- CR effective date not moved forward to parent study

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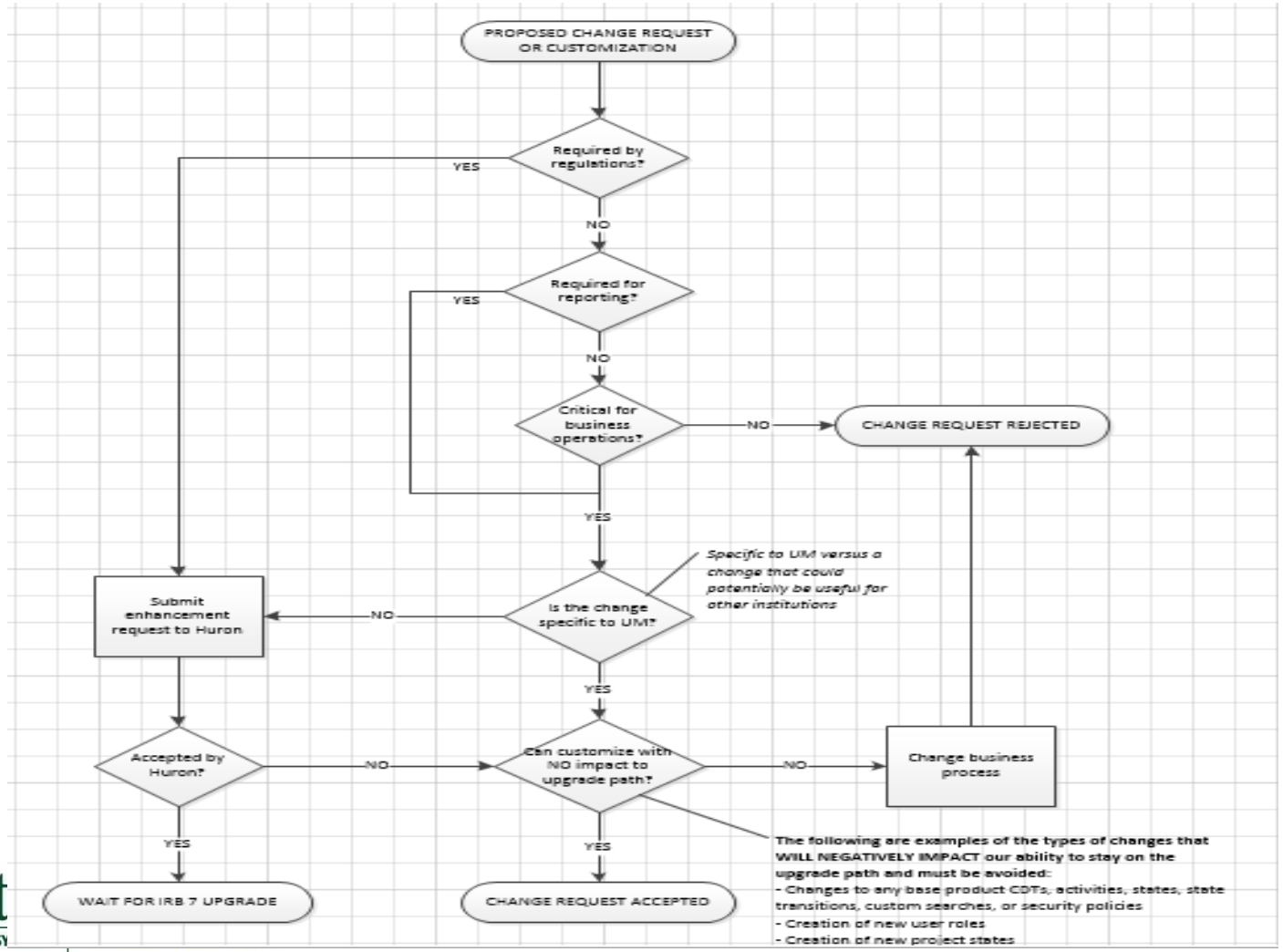
Evaluation of IRB 7 Configuration Change Requests



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Guidelines for IRB7 Customizations

Type of Change	Changes CAN be made:	Changes CANNOT be made:
SmartForm	▪ Add new pages to existing SmartForm, but only between Consent Forms page and Supporting Documents page ○ Additional Study Information ○ Medical Studies Only ○ Jackson Studies	▪ Basic Information ▪ External IRB ▪ Funding Sources ▪ Study Team Members ▪ Study Scope ▪ External Sites ▪ Drugs ▪ Devices ▪ Consent Forms & Recruitment Materials ▪ Supporting Documents ▪ Modification/CR ▪ RNI
Activities	▪ Add new activity, as long as it does not affect workflow (i.e. no state transitions) ○ Update Billing Information ○ Create Follow On RNI ○ Update UMH/JHS Enrollment	▪ Add Comment ▪ Assign Primary Contact, PI Proxy ▪ Copy Submission ▪ Discard, Withdraw ▪ Manage Guest List ▪ Submit, Submit RNI ▪ Submit Changes, Submit RNI Changes

Upgrade Overview

- **Upgrading to the latest version,IRB7 v7.6 , from v7.3 : Total 6 releases**
- **Metrics of Enhancements and Resolved Issues:**

Criteria	Enhancements	Issues	Unidentified	Total
Total items addressed with Upgrade (includes all items listed below)	82	147	50	*279

** Approximately 40 are UM specific*

- **Estimated release Fall 2015**

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Preview of New Features

- **Notifications Selection feature on Add Comment Activities**
  Users will now have the ability to select who receives an email notification when Add Comment activities are executed.
- **Notify PI Proxy as well as PI**
  Improved notifications to include the PI proxy if notifying PI.
- **Ability to Open the Role of IRB Coordinator**
  IRB staff will be able to make minor study edits in states where only Study Staff could previously edit.
- **Updated Continuing Review Research milestones**
  Question #1 selection items (on Continuing Review Smart Form) have been updated for clarity.
- **"Date Entered IRB" always shows 12:00AM in study workspace**
  The Date Entered IRB is set to show when an IRB Submission or an RNI is submitted.

Preview of New Features

- **Introduction of a Snapshots tab in Follow-On Submission workspace**
  When MOD/MODCR/CR is submitted, or approved, or changes are submitted, a snapshot will now be created and the snapshot can be accessed from the Snapshots tab on the Modification or Continuing Review workspace.
- **MOD Printer Version enhancement**
  Printer Version in the Modification workspace now includes both the Old and New changes to the Modification Smart Form. Previously only the Modification or Continuing Review steps were included.
- **New Funding Tab added to study workspace**
- **Redesigned RNI workflow**
  The RNI workflow is now more similar to IRB Study workflow, and also provides an Action Required loop to allow tracking for RNI follow up items.

Redesigned RNI Workflow

The RNI workflow uses similar states to a study, but the IRB review process routes the submission differently depending on the significance of the determinations selected. This reduces the IRB's time spent handling insignificant issues. The rules are:

- When an RNI submission is **not** considered a serious* issue, the submission transitions directly to the Acknowledged state and sends an e-mail notification indicating that the review is complete.

- Any RNI submission that represents a serious* issue must eventually go through committee review to determine any follow-up actions. After committee review, serious* submissions go to the Post-Review state so the coordinator can prepare and send a letter. Furthermore, the committee can now require follow-up actions to resolve the issue called an *"Action Plan".*

Redesigned RNI Workflow: Activities

- **Created new "Add Related submission" activity for RNI**
  There is a new activity which allows the user to associate submissions and modifications to a Reportable New Information submission (through the RNI workspace and the RNI Smart Form)
- **Created new "Assign Responsible Party" activity**
  There is a new activity to allow IRB to assign a responsible party to complete any required action for a Reportable New Information.
- **Created new "Submit Action Response" Activity**
  Reportable New Information now has an action required and verification loop
- **Renamed activity from "Submit Changes" to "Submit Response"**
  "Submit Changes" activities are now "Submit Response" to more accurately describe the action (for RNI workflow only)
- **Created new "Submit RNI Designated Review" activity**
  Reportable New Information now has designated review similar to Study submissions

RNI Redesign – Add Related Studies Field

- **Updated Field on RNI Smart Form**

6. Related studies and modifications:

Add

ID	Short Title	Investigator	State	IRB Office

There are no items to display

6. Related studies and modifications:

Add

ID	Short Title	Investigator	State	IRB Office	
STUDY00000064	Nortriptyline Use in Children with FMS	Rebecca Simms (pi)	Approved	Medical Center IRB	Remove

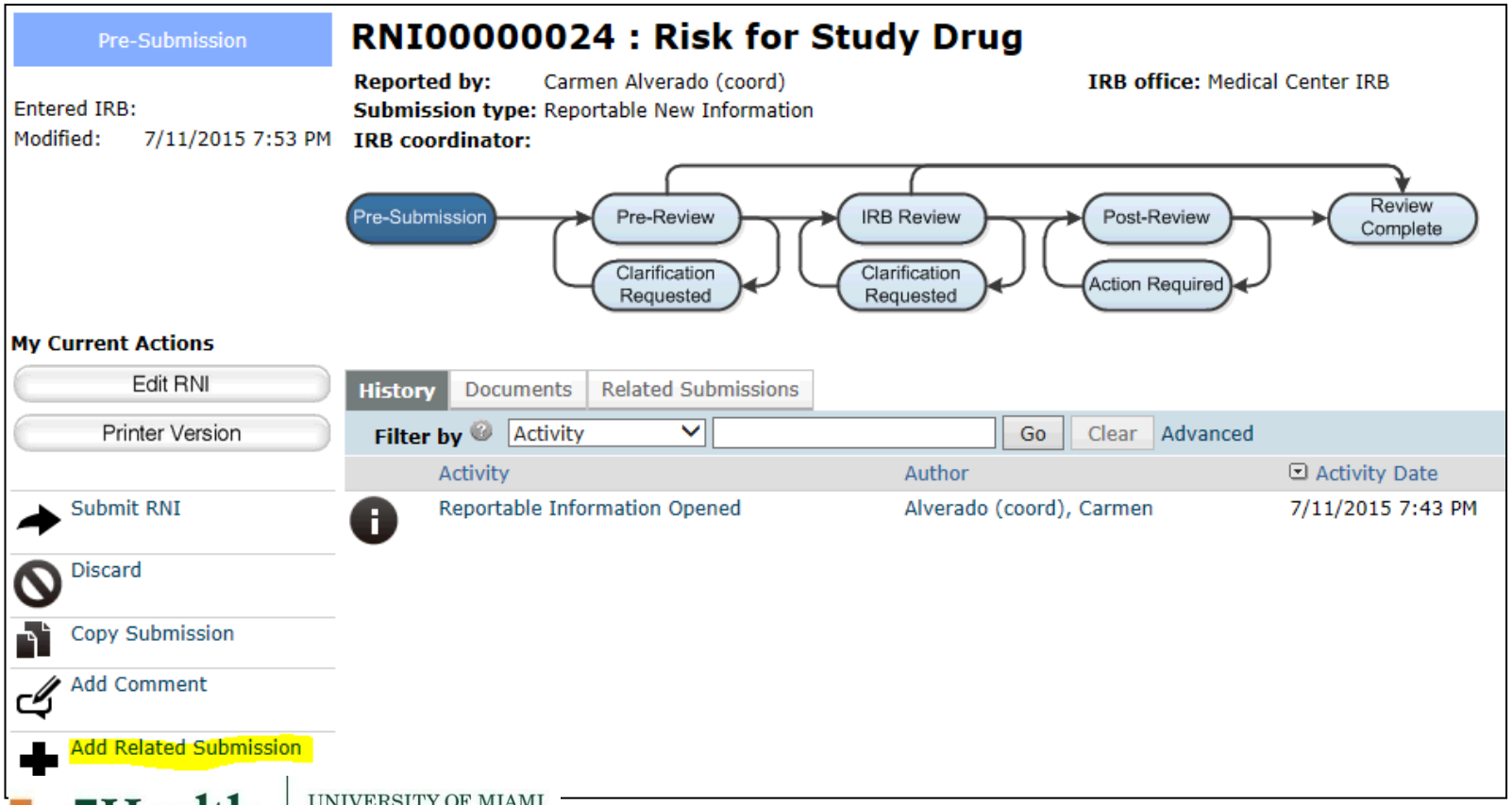
6. Related studies and modifications:

Add

ID	Short Title	Investigator	State	IRB Office	
MOD00000010	Modification #1 for Study STUDY00000064		Pre-Submission	Medical Center IRB	Remove
MOD00000011	Modification #2 for Study STUDY00000064		Pre-Submission	Medical Center IRB	Remove
STUDY00000064	Nortriptyline Use in Children with FMS	Rebecca Simms (pi)	Approved	Medical Center IRB	Remove

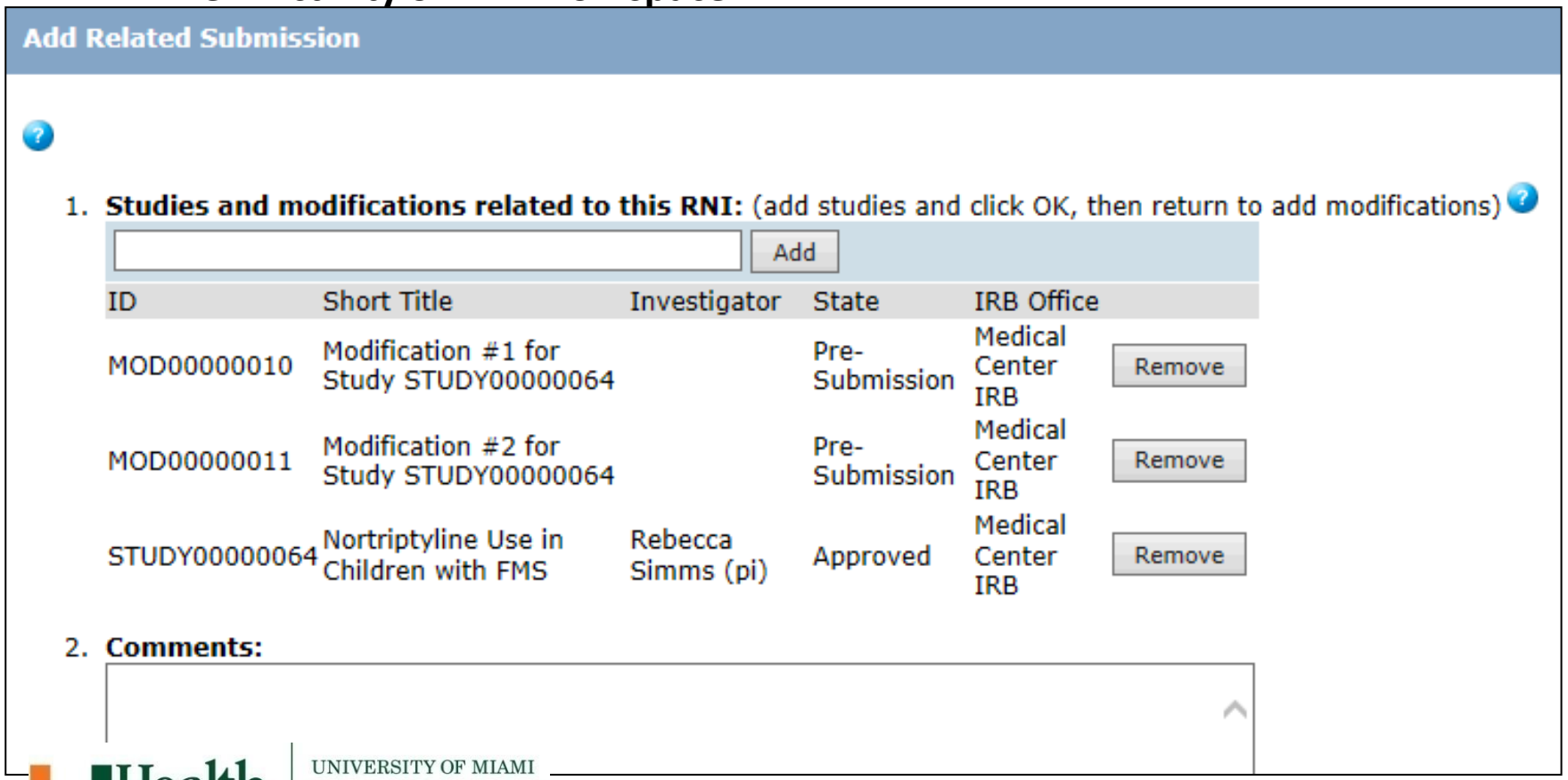
RNI Redesign – Add Related Submission Activity

- **New Activity on RNI workspace**



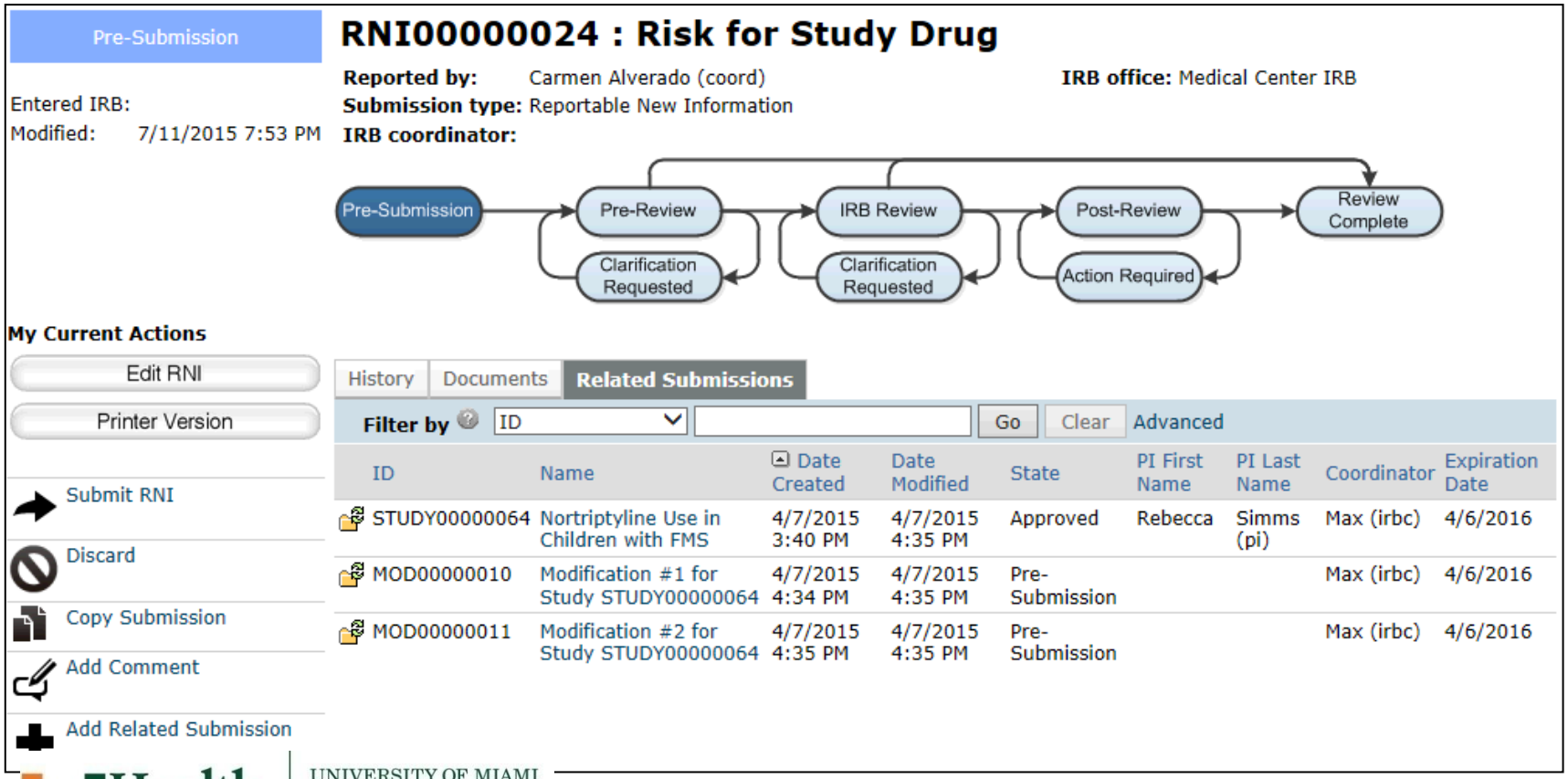
RNI Redesign – Add Related Submission Activity

- **New Activity on RNI workspace**



RNI Redesign –Related Submission Tab

- **Updated tab on RNI workspace**



Redesigned RNI Workflow: Activities

- **Created new "Add Related submission" activity for RNI**
  There is a new activity which allows the user to associate submissions and modifications to a Reportable New Information submission (through the RNI workspace and the RNI Smart Form)
- **Created new "Assign Responsible Party" activity**
  There is a new activity to allow IRB to assign a responsible party to complete any required action for a Reportable New Information *when RNI is considered a serious issue.*
- **Created new "Submit Action Response" Activity**
  Reportable New Information now has an action required and verification loop
- **Renamed activity from "Submit Changes" to "Submit Response"**
  "Submit Changes" activities are now "Submit Response" to more accurately describe the action (for RNI workflow only)
- **Created new "Submit RNI Designated Review" activity**
  Reportable New Information now has designated review similar to Study submissions

RNI Redesign – Responsible Party

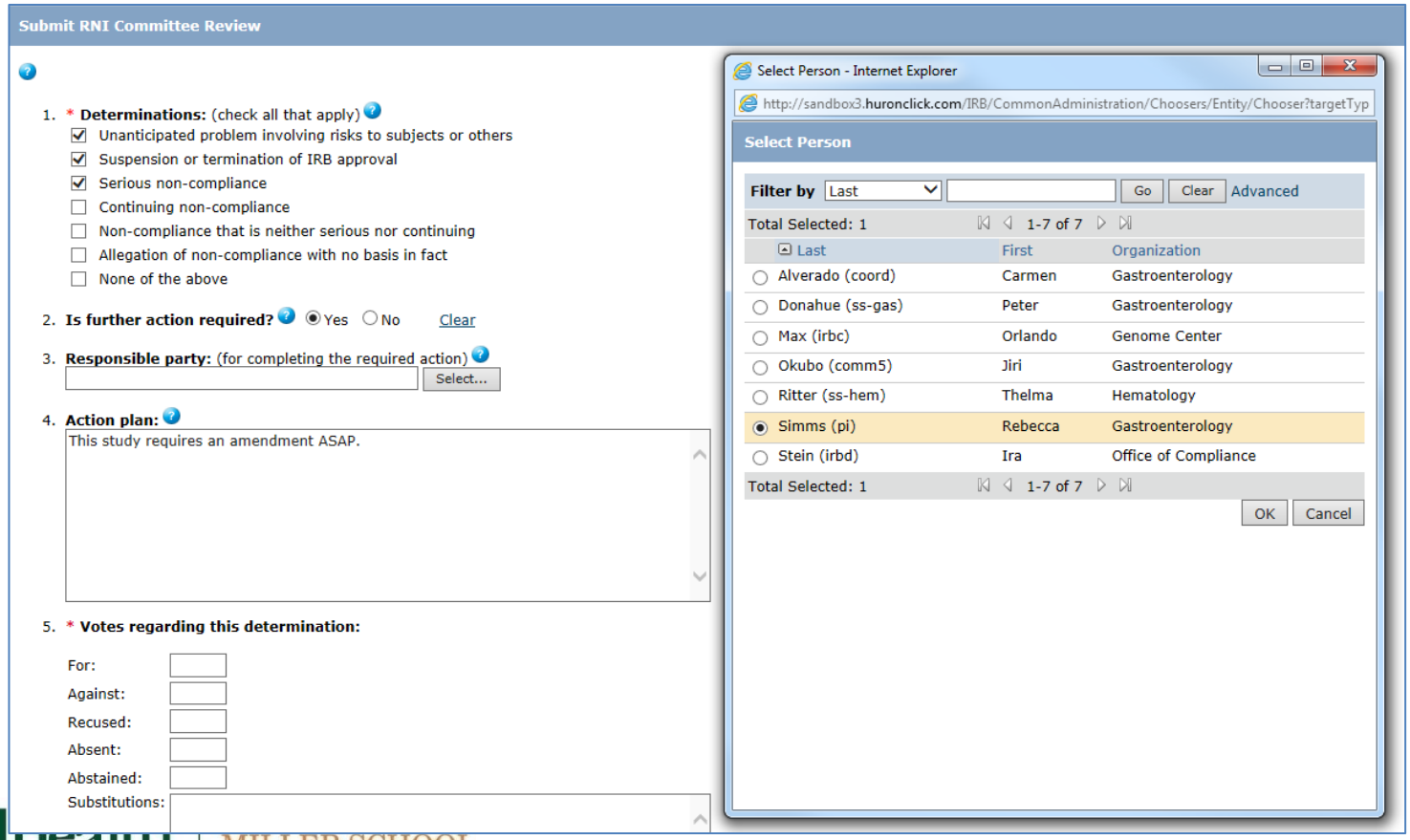
- **If RNI is reviewed by a Committee, follow-up actions may be required to resolve the issue.**

  Question: Is Further Action Required?

  - Define the action plan
  - Assign the person responsible for completing the action plan
  - Notify the responsible party and others related to this RNI regarding the actions needed
  - Review the action plan when it is reported as completed before closing the RNI

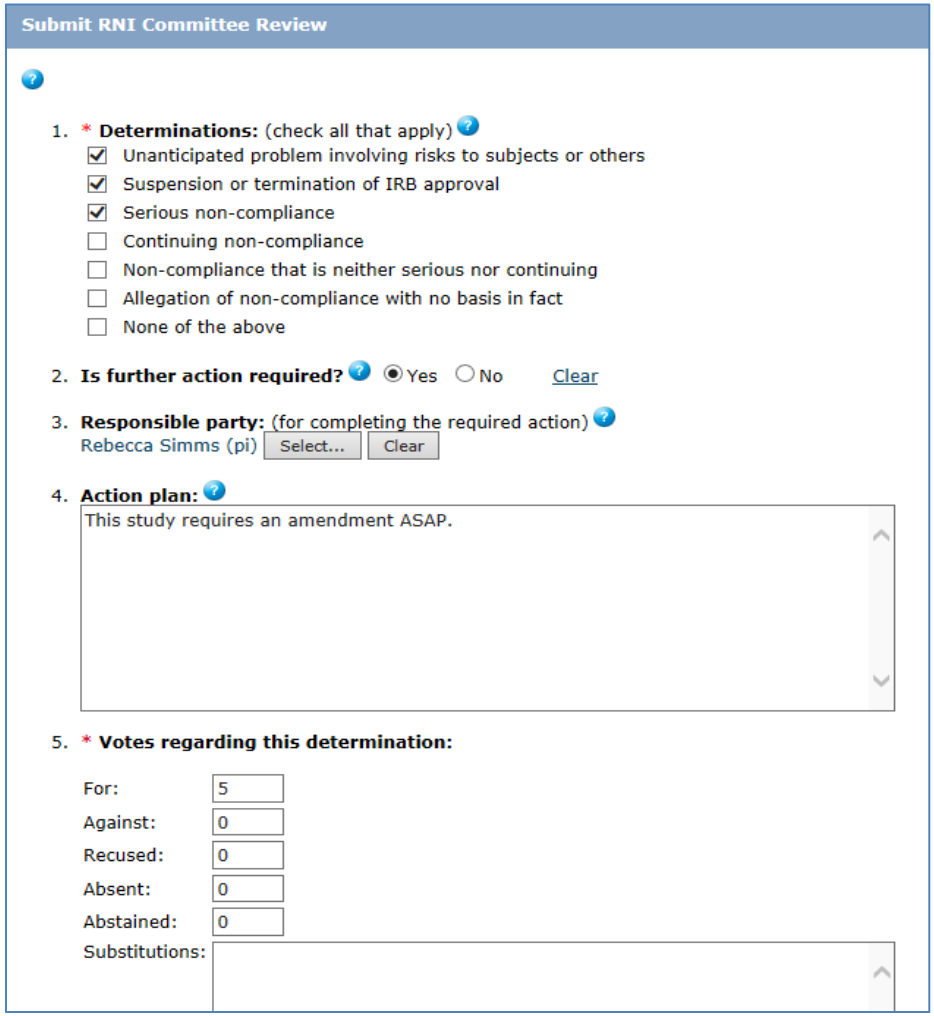
RNI Redesign – Responsible Party Workflow

Logged in as IRB Coordinator (assign responsible party)



RNI Redesign – Responsible Party Workflow

Responsible Party: Rebecca Sims



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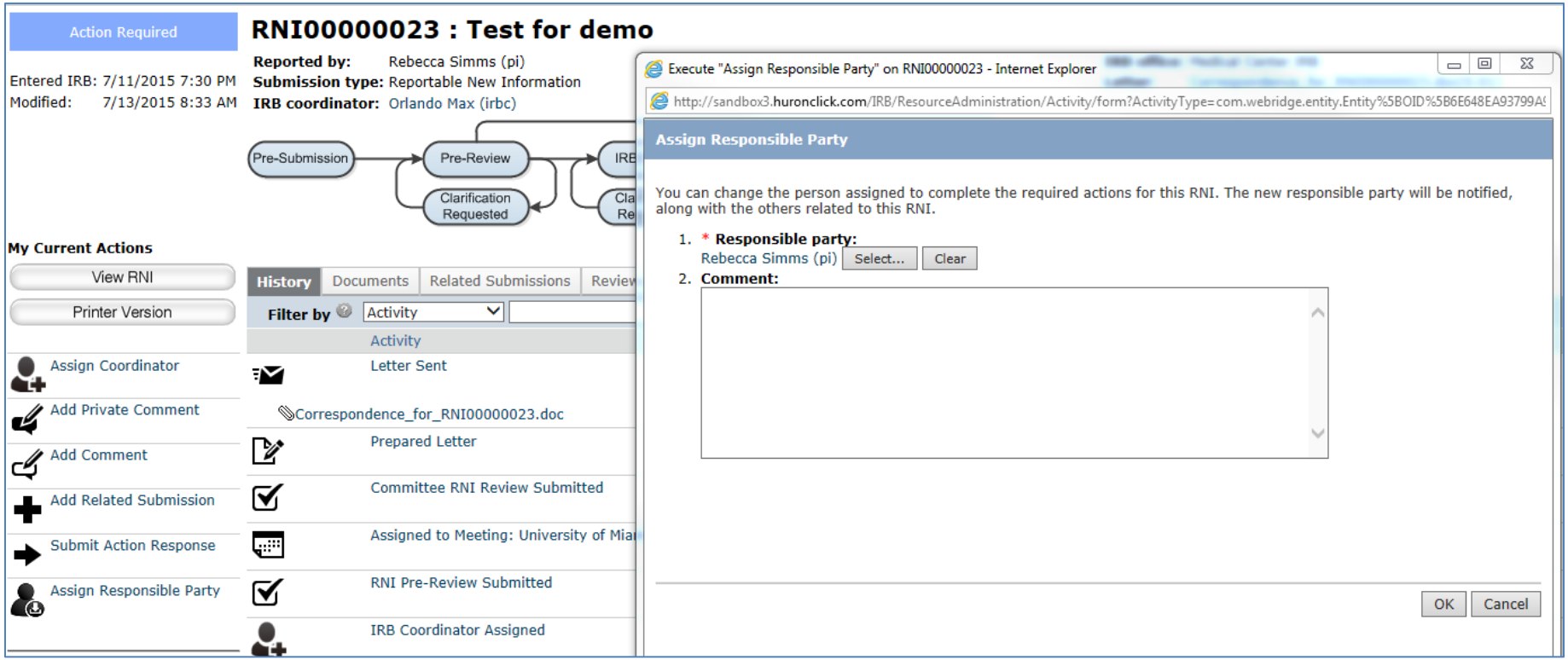
RNI Redesign – Responsible Party Workflow

Responsible Party *may be* reassigned



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Redesigned RNI Workflow: Activities

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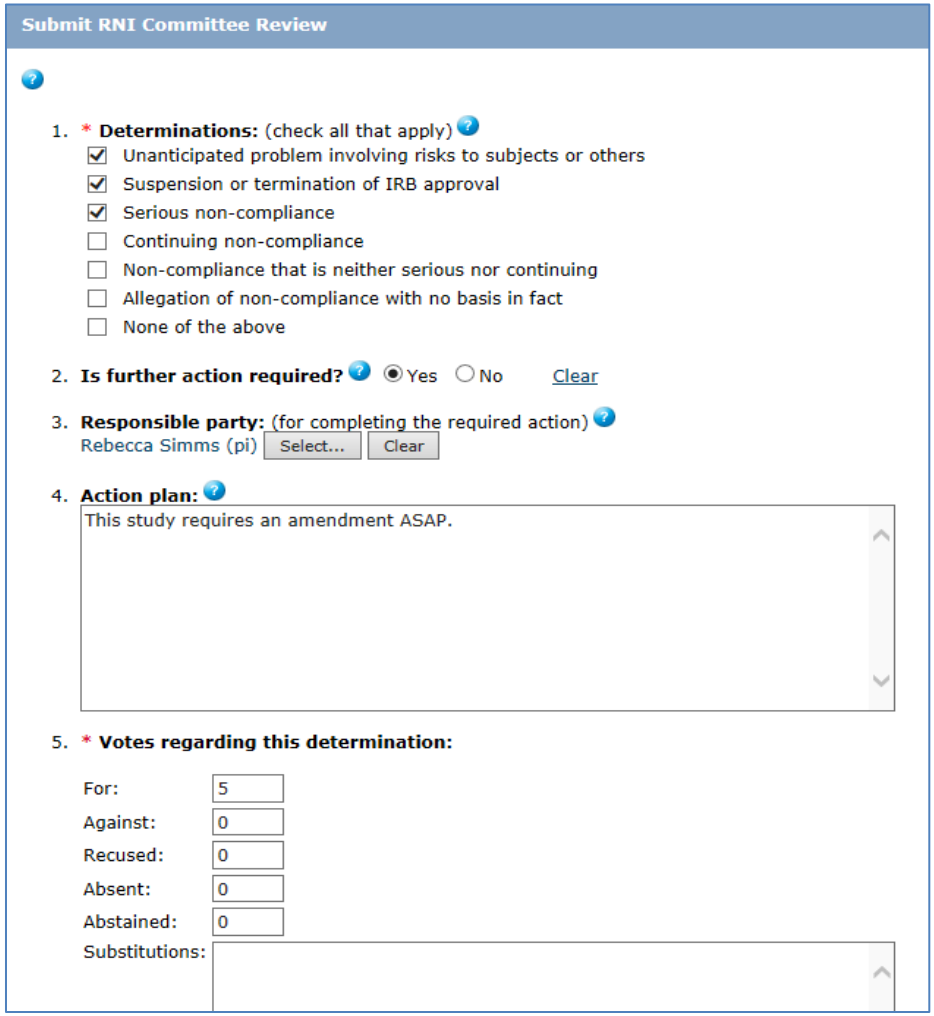
  There is a new activity which allows the user to associate submissions and modifications to a Reportable New Information submission (through the RNI workspace and the RNI Smart Form)
- **Created new "Assign Responsible Party" activity**
  There is a new activity to allow IRB to assign a responsible party to complete any required action for a Reportable New Information.
- **Created new "Submit Action Response" Activity**
  Reportable New Information now has an action required and verification loop *when an Action Plan exists.*
- **Renamed activity from "Submit RNI Changes" to "Submit Response"**
  "Submit RNI Changes" activities are now "Submit Response" to more accurately describe the action (for RNI workflow only) when responding *to clarifications requested.*

Redesigned RNI Workflow: Workspace

- **Created new Action Plan tab for RNI**
  To support the New Reportable Information workflow changes, there is a new tab to show both the Action Plan and the Responsible Party who needs to complete it, as well as any changes which have occurred to it.
- **Updated RNI access for associated study team**
  For Reportable New Information submissions, any related studies' associated PI, study team members, PI proxy and primary contact are now able to view the submission, regardless of how RNI was created.
- **Updated RNI workspace**
  Updated RNI workspace to display any related Modifications
- **Updated RNI so it remains in Complete state appropriately**
  When an RNI is in Complete state, it will now only transition to Post-Review if there is an action required and not completed, or if it changed from having significant determinations to only insignificant determinations.

RNI Redesign – Action Plan

Responsible Party: Rebecca Sims



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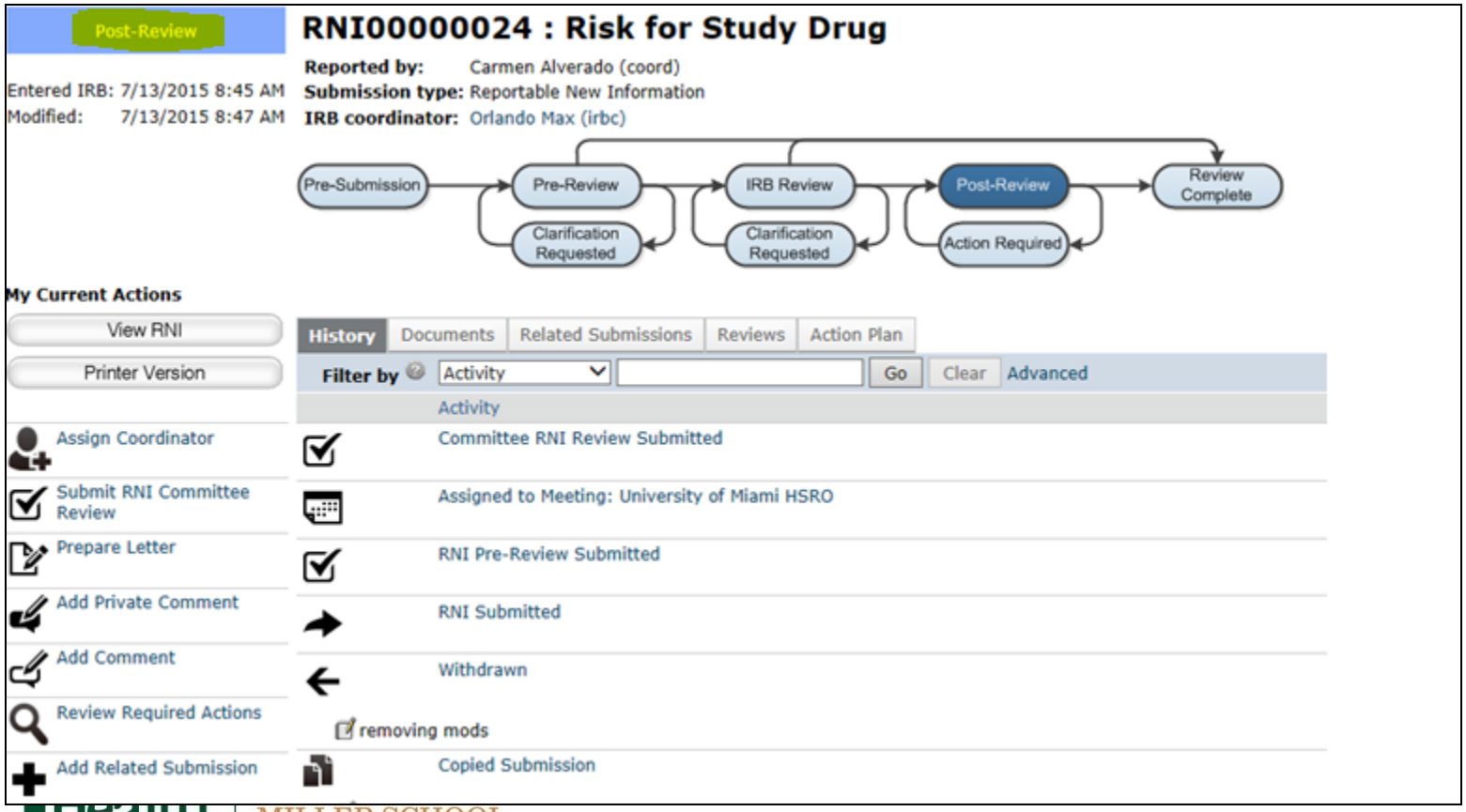
RNI Redesign – Action Plan

- **Is Further Action Required?**
  - Selecting "Yes" enables the Committee to:
    - Define the action plan
    - Assign the person responsible for completing the action plan
    - Notify the responsible party and others related to this RNI regarding the actions needed
    - Review the action plan when it is reported as completed before closing the RNI

RNI Redesign – Action Plan Workflow

Logged in as an IRB Coordinator (after assigning responsible party)



RNI Redesign – Action Plan Workflow

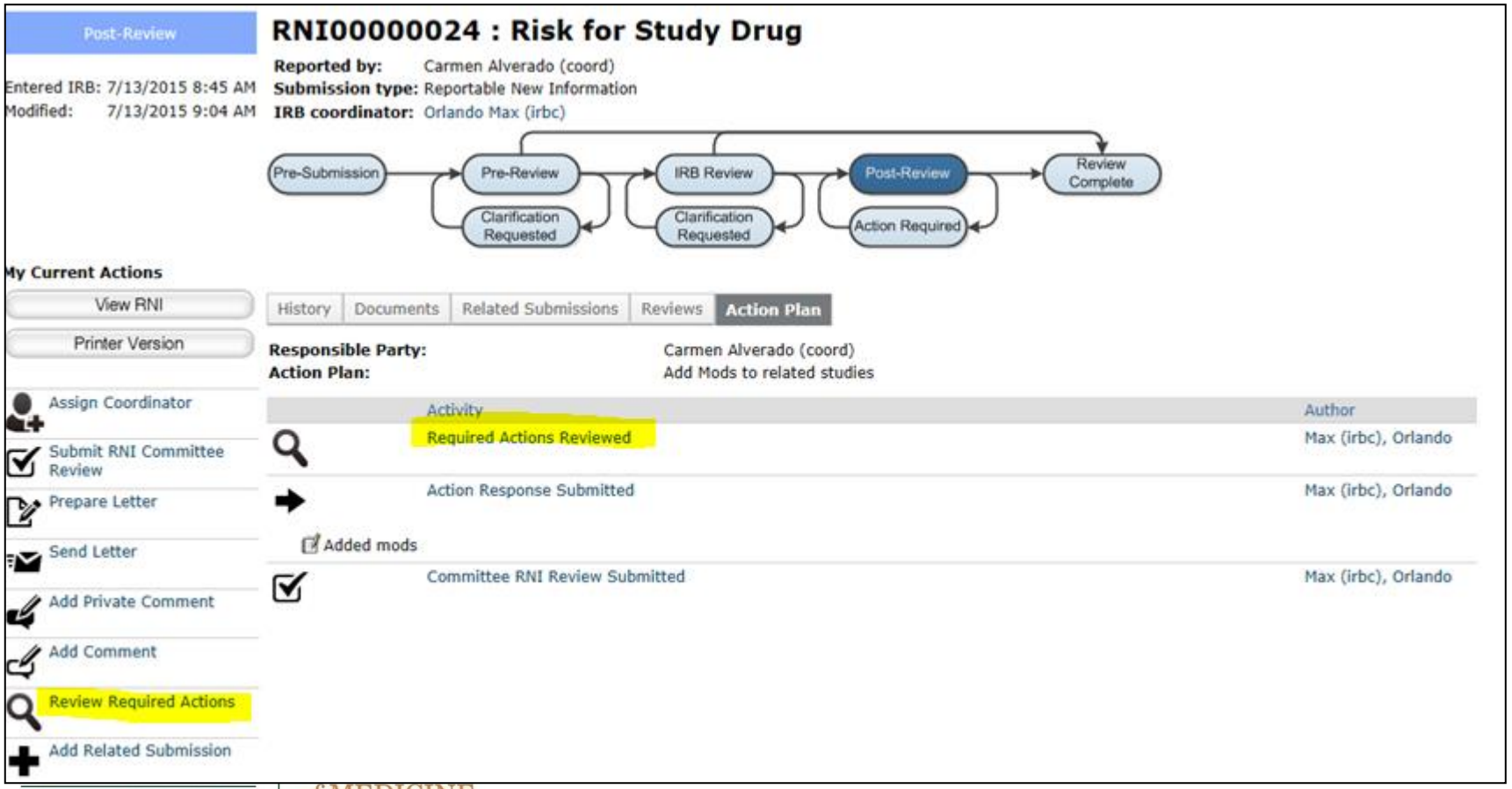
Logged in as an IRB Coordinator (after prepare and send letter)

RNI Redesign – Action Plan Tab

Logged in as the PI (Submit Action Response)

RNI Redesign – Action Plan Tab

Logged in as an IRB Coordinator (required actions reviewed)



Redesigned RNI Workflow: Workspace

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- **Updated RNI access for associated study team**
  For Reportable New Information submissions, any related studies' associated PI, study team members, PI proxy and primary contact are now able to view the submission.
- **Updated RNI so it remains in Complete state appropriately**
  When an RNI is in Complete state, it will now only transition to Post-Review if there is an action required and not completed, or if it changed from having significant determinations to only insignificant determinations.

Redesigned RNI Workflow: Notifications

- **RNI Letter modifications**
  Reportable New Information letter shows action plan, if required. Additionally, removed Funding, IND, IDE or HDE and documents reviewed, as these do not apply to the reportable new information process
- **Created new RNI email notifications**
  There are now new Reportable New Information email templates for Clarifications Requested, Send to Designated Reviewer, and Response Time Exceeded.

RNI Business Process

Amanda Coltes

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RNI Current Business Process

- **Review of RNI form**
- **Review of HSRO/IRB workflow**

Reportable New Information

When viewing items in your Inbox or on the IRB Workspace, RNI Short Title will show up under the "Name" column

1. **RNI short title:** (uniquely identify this new information report)

2. * **Date you became aware of the information:**

List date study team became aware of the RNI

3. **Identify the categories that represent the new information:** (check all that apply)

☐ **Risk:** Information that indicates a new or increased risk, or a safety issue. For example:

a. New information (e.g., an interim analysis, safety monitoring report, publication in the literature, sponsor report, or investigator finding) indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.

b. An investigator brochure, package insert, or device labeling is revised to indicate an increase in the frequency or magnitude of a previously known risk, or to describe a new risk.

c. Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.

d. Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.

e. Complaint of a subject that indicates subjects or others might be at increased risk of harm or at risk of a new harm.

f. Any changes significantly affecting the conduct of the research. frequency, and characteristics of the study population.

b. A harm is "**probably related**" to the research procedures if, in the opinion of the investigator, the research procedures more likely than not caused the harm.

☐ **Non-compliance:** Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.

RNI includes unanticipated problems, newly identified risks, adverse events (unexpected and probably related), deviations and violations, audit or monitoring results, etc.

RNIs do not include expected or unrelated AEs, IND Safety Reports, Translations, Sponsor Letters without impact on risks, etc.

5. **In the PI's opinion:**

   a. * **Does this information indicate a new or increased risk, or a safety issue?**
   ○ Yes ○ No Clear

   b. * **Does the study need revision?**
   ○ Yes ○ No Clear

   c. * **Does the consent document need revision?**
   ○ Yes ○ No Clear

Select Yes or No based on PI's review of the RNI

If revisions are required, describe them above and submit a study modification for review.

6. **Related Studies:**

Add

ID	Short Title	Investigator	State	IRB Office
There are no items to display				

You will be able to list as many studies (and modifications) as are affected. *(E.g. PI is involved in multiple studies involving the same drug.)*

7. **Attach files containing supporting information:**

Add

Name
There are no items to display

Upload documents as appropriate

<< Back Save| | Print... Continue >>

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b. A harm is "**probably related**" to the research procedures if, in the opinion of the investigator, the research procedures more likely than not caused the harm.

- ☐ **Non-compliance:** Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
- ☐ **Audit:** Audit, inspection, or inquiry by a federal agency.
- ☐ **Report:** Written reports of study monitors.
- ☐ **Researcher error:** Failure to follow the protocol due to the action or inaction of the investigator or research staff.
- ☐ **Confidentiality:** Breach of confidentiality.
- ☐ **Unreviewed change:** Change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a subject.
- ☐ **Incarceration:** Incarceration of a subject in a study not approved by the IRB to involve prisoners.
- ☐ **Complaint:** Complaint of a subject that cannot be resolved by the research team.
- ☐ **Suspension:** Premature suspension or termination of the research by the sponsor, investigator, or institution.
- ☐ **Unanticipated adverse device effect:** Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

Important! Information that does not fit into one of the categories above does not need to be reported to the IRB as new information.

4. * **Briefly describe the new information:**

Summary of RNI

5. **In the PI's opinion:**

Workflow

- To avoid a large influx of non-compliance reports, Investigator Manual indicates:
  - Non-compliance (i.e. protocol deviation) must be reported via the RNI form if it may:

    i) impact subject safety, condition or status;

    ii) affect the integrity of study data;

    iii) pose a significant risk of harm and thereby change the risk/benefit ratio; and/or

    iv) affect a subject's willingness to participate in the study.
  - Non-compliance (i.e. protocol deviations) not meeting the above criteria must be reported in summary format at the time of continuing review.

Workflow

- Once RNI is submitted, it enters the 'RNI Review' state
  - Review by HSRO staff:
    - May request clarifications
    - If report is not risk-relevant, it is assigned to a Designated Reviewer.
      - If reviewer agrees, determination is made and letter sent.
      - If reviewer disagrees, it is assigned to Committee Review.
    - If report is risk relevant, it is assigned to Committee Review.
      - Committee makes determination
      - Determination letter sent

Reporting Timeframe

- Report the information items that fall into one or more of the above categories to the IRB within 10 business days using the RNI form.
- *Information that does not fall under any of the categories does not require reporting to the IRB.*
  - *Additional guidance found in Investigator Manual (HRP-103)*

Things to Remember

- Currently:
  - Only person who creates RNI is able to view and manage it.
  - PI will not receive notification that RNI was submitted or of the change requests.
- With upgrade:
  - PI of any related studies, study team members, PI proxy and primary contact will be able to view the submission.

Things to Remember

- An RNI submission can be associated with one or more studies, or with no study at all.
  - Limit associations to studies by the same PI and under review by the same IRB.

Questions

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Thank You

IRB7 at University of Miami
Managed by Research IT
2nd floor, Sieron Building

IRB7 HelpDesk: Technical matters, account requests
eprost@med.miami.edu
305-243-2314

HSRO HelpDesk: Training and Regulatory assistance
305-243-3195