



# Rascal IRB 2.0 Release

May 11, 2015

*Brenda Ruotolo, Executive Director, HRPO*  
*Alan Teller, Assoc. Dir., Operations, HRPO*



**raStaj**

**IRB 2.0**

**MAY 31, 2015**



# May 31, 2015 (Sunday)

- IRB 1.0 replaced by IRB 2.0 overnight
  - Timing TBD
- No noticeable Rascal shut down
- June 1, 2015 (Monday): New IRB screens/fields/questions
- ALL new fields will be required for ALL protocols as part of the first submission after May 31, 2015
  - Same system – one version replacing the other
  - New fields not accessible until 2.0 is live

# IRB 2.0 Goals

## *Reduce turnaround time without compromising quality*

Obtain more complete applications – reduce returns

- **55%** of all new protocols are returned at pre-review
- **66%** of exempt/expedited protocols are returned at pre-review
- Average returns for new protocols: **2.1**  
(including external reviews, e.g. PRMC, JRSC, IBC, COI)

Directed logic driven questions with less narrative text required

Address researchers' requests

Upgrade to the investigator interface (only)

# Goals (continued)

Provide explanations and Help Text



Enhance IRB ability to meet regulatory requirements

- IRB module initially released March 2003

Facilitate ability to run more reports

- Researchers and HRPO/IRB

Streamline review process and set up for IRB 2.1 (IRB side)

Requests that could not be incorporated into 2.0 will be assimilated in monthly releases

- IRB “bug” list was 100+ items

# Status of Rascal IRB 2.0



- Testing of the composite module is underway
- *Researcher feedback has been helpful – thank you!*
- Working with units that receive data from Rascal
  - E.g., HICCC, IBC, JRSO/RSO, RCT (COI)
- Finalized approval requirements
- Scheduled many more lab/consultation/demo sessions
  - Staging phase (TBA) will allow look at active protocols

# Outreach Efforts

- April 3<sup>rd</sup> and May 11th Listserv messages
- Emails to department heads and DAs
- IRB staff email tag line
- IRB correspondence (Rascal)
- CUMC/MS MIMs

## Sessions for departments, personnel

- Peds faculty ✓ Adol Med ✓ CDM ✓ Taub/Sergievsky ✓
- Business School ✓ DOM Division Chiefs/faculty ✓

# Follows the IRB Review Process

Application flow will mirror the way protocols are reviewed

- Research

- Human Subjects

- Exempt

- » Expedited

Specific pages for specific research components

Built-in “I don’t know” responses

New pages



# Identify Special Circumstances

New “Attributes” page identifies submission features that may affect triage/Board assignment

- Special funding circumstances

- HS procedures don’t start immediately
- Training/Center grant

- IRB Reliance Agreements

- Multi-center trials

- Roles e.g., Coordinating Center/Lead Site/Repository
- Responsibilities

- University Resources used

# Prompts and Validations

Many more required fields

- Page and submit validations
- Individual pages cannot be saved until required information is provided
- Validations between pages will identify inconsistencies and/or missing items prior to submission

# Stand-alone\* Protocols

Certain questions/sections designed to allow for referral to protocols built outside of Rascal (e.g. sponsor's protocols, grants, multi-center or externally developed protocols)

The current "Study Description" is going away

- All related fields are incorporated into individual pages
- *If accurate and comprehensive*, can be "Stand-alone"

*\*Document that describes some/all aspects of the study (e.g., sponsor's protocol, grant application, dissertation) and will be attached to your Rascal IRB submission*

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*All previously approved submissions will remain the same*

## Currently...

<b>Status:</b>	<b>Submitted</b>
<b>IRB Committee:</b>	<b>IRB 1</b>
<b>Exempt:</b>	<b>No</b>
<b>Expeditable:</b>	<b>No</b>
<b>Meeting Date:</b>	
<b>Possible COI Anomaly:</b>	<b>No</b>
<b>IRB Approval Date:</b>	
<b>Expiration Date:</b>	

## Status History

Status	Date
<a href="#">Submitted</a>	04/06/2015 at 14:52
<a href="#">Returned</a>	03/06/2015 at 15:12
<a href="#">Submitted</a>	03/04/2015 at 13:16
<a href="#">Creating</a>	02/18/2015 at 15:31





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First submission after  
May 31, 2015:

ALL new fields will be  
required for ALL

*protocols, renewals, mods*  
*(submission & resubmission)*

# Events\* in Researcher Queues

- At the time of transition:
  - **existing data** in fields in the current submission that do not map directly to fields in the new system **will be cleared**
    - all previously approved submissions will be unaffected
    - all previously submitted versions will be unaffected
- New fields will appear and require completion before submission
- *Tip: Save text in Study Description for “creating” events*

*\*Event = protocol, modification, renewal, UP, closure*



# Events in the IRB Queues

- If returned prior to approval:
  - Information in non-mapped fields will be cleared upon return
  - New fields will appear and completion will be required before re-submission
- If approved without being returned:
  - IRB 2.0 fields will not appear until a renewal or modification is created



# Planning: New Protocols

Protocols currently in process (creating, returned, pending)

- Submit/re-submit asap to obtain approval before go-live date

Protocols not yet created in Rascal

- Consider the target go-live date
  - Requiring review at a convened meeting:
    - Suggest waiting until June 1 to submit
  - Expedited or exempt (i.e., low risk)
    - Consider time sensitivity; wait if possible
  - Be prepared to re-submit quickly if returned during review

# Renewals

- Consider expiration dates
  - May/June: should already be submitted
  - July expedited/exempt: can probably wait until June 1
  - July “full board”: toss up!
    - No changes, no issues: submit by May 31
    - Changes, issues: submit after June 1
- Creation/submission at any time after the go-live date will require completion of ALL new fields before submission
  - regardless of expiration date

*Trying to avoid completion in 2 formats (if return)*

# Modifications

- Completion of ALL new fields will be required for any modification, no matter how minor, if it is the first event submitted after go-live date
- Consider NOW what modifications are foreseeable and create those asap

## Unanticipated Problems reports & Closures

- New fields not required
- UPs – improved format
- Closures – additional questions

# IRB Meeting Schedule

**HRPO staff and IRB members will not be able to process all protocols if they are submitted right before the deadline.  
Start early!**

## **IRB Convened Meeting Dates**

**IRBs 2 & 3:**

**5/27, 6/10, 6/24, 7/8, 7/22**

**IRBs 1 & 4:**

**5/20, 6/3, 6/17, 7/1, 7/15, 7/29**

*Agendas close one week  
prior to each meeting*



# Plan Ahead!

- Stay tuned for future updates/sessions/trainings
- Assess all current and potential future submissions for timing
- *Be prepared that old protocols may require additional information that has not previously been required/requested*
- Contact HRPO staff with questions and/or if you would like to be involved in the final rounds of testing.

# Information/Demos/Help

## Presentations:

- P&S Amphitheatre 7; Thursdays 3:30 - 4:30 pm
- May 14th: Monthly
- May 28th: Rascal 2.0 Demo

## IRB Walk-In Consultation

- 154 Haven Ave, 1<sup>st</sup> Floor: Tuesdays 10-11 am

## IRB Liaison Service (Rui Ferreira) *New!*

- *Walk-in:* PH 10-402: Wednesdays and Thursdays 10-11 am
- By appointment: **342-5136**; [rf2554@cumc.columbia.edu](mailto:rf2554@cumc.columbia.edu)



# Walk-in Computer Lab Consultation Hours

## *Demos – Assistance with planning - staging*

- **10:30-11:30 am, Hammer 202A: Friday, 5/22**
- **Additional sessions to be disseminated via listserv**

# Questions?

Medical Center HRPO:

- [irboffice@columbia.edu](mailto:irboffice@columbia.edu)
- 212-305-5883

HRPO Staff:

<http://www.cumc.columbia.edu/dept/irb/documents/RBStaffDirectoryexternal9.15.2014.pdf>

