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 3rd 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*
All previously approved submissions will remain the same
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, 1st 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
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
  – 212-305-5883

HRPO Staff: