HRPO/IRB Updates
March 26, 2015

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Agenda

• Incidental Findings Policy revision
• Students as Researchers Policy revision – draft
• Review of combined consent/authorization forms
• Rascal IRB 2.0 status
• How researchers need to prepare for IRB 2.0

Incidental Findings Policy revised

Changes:
• Applicability: modifications to protocols approved before Aug. 7, 2012, to include or revise imaging procedures, now included
• Requirement for imaging done at Columbia to be reviewed by a certified radiologist at Columbia unless otherwise approved by the Dept. of Radiology
• Clarification: “documentation by the Dept. of Radiology that review…two weeks.” replaces “Documentation…Radiology, utilizing the Reporting of Incidental Findings in Research Form…”
• Clarification: Reporting of IF should be on the Reporting of IF form
Current Students as Researchers Policy

All research activities involving human subjects and conducted by Columbia students must be approved by the IRB prior to the initiation of the research activity.

Except for:
Low Risk Introductory Research Methodology Exercises

- Campus/public setting
- Learning research methodology
- Minimal risk
- Anonymous data collection

Draft revised Policy

Responsibility for determining level of risk and whether a project requires IRB review rests with the student’s faculty advisor and/or department.

Student projects, e.g., introductory research exercises or practicum assignments, must be reviewed and approved by … IRB when they involve greater than minimal risk of harm to participants, to provide increased protection to the participants.

Anticipated release date: Early April 2015

Combined forms process change

Review of combined consent and authorization forms is being transitioned to the IRB

What does this mean for you?
• Eliminates the need to route the form to the Privacy Office for approval
• HiPAA language is being incorporated into the Rascal CF Builder

Target date for transition: April 15, 2015
Status of Rascal IRB 2.0

- Specifications nearly done
- Testing of most screens has occurred
- Testing of the entire revised module is imminent
- Working with units that receive data from Rascal
- Reviewing approval requirements

Two months notice when go-live date is determined
- Go-live date may be as soon as May 28, 2015

IRB 2.0 Goals

Upgrade to the investigator interface (only)
Obtain more complete applications – reduce returns
- 55% of all new protocols are returned at pre-review
- 66% of exempt and expedited protocols are returned at pre-review
- On average a protocol is submitted 2.1 times before approval (including external reviews, e.g. PRMC, JRSC, IBC)

Reduce turnaround time without compromising quality
Ask directed logic driven questions with less narrative text required
Enhance IRB ability to meet regulatory requirements
Facilitate ability to run more reports
Streamline review process and set up for IRB 2.1 (IRB side)

Read! Read! Read!
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
Build-in “I don’t know” responses
New pages
Information to explain questions; revised help text

Identify Special Circumstances

New “Attributes” page identifies submission features that may affect triage/Board assignment
- Special funding circumstances
- IRB Reliance Agreements
- Multi-center trials
  - 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 the 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

ALL new fields will be required for ALL protocols as part of the first submission after the new system goes live

Events being created

• On the go live date:
  • existing data in fields in the current submission that do not map directly to fields in the new system will be cleared (i.e., all previously approved submissions will remain the same)
  • New fields will appear and require completion before submission
Events under review

- If in an IRB queue on the go-live date:
  - If returned by HRPO staff or the IRB, information in non-mapped fields will be cleared upon return
  - New fields will appear and completion will be required before re-submission
- If returned on the go-live date:
  - Information in non-mapped fields will be cleared
  - New fields will appear and completion will be required before re-submission

What about your 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
    - can you wait until after the roll-out?
    - If approval is urgent, submit ASAP!
    - Be prepared to re-submit quickly if returned during review

831 Returned or Pending Protocols

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

Renewals

- Consider expiration dates
  - April: should already be submitted
  - May/June: should be submitted soon to allow processing time prior to the go-live date
  - July: submit no later than May
- Creation/submission at any time after the go-live date will require completion of ALL new fields before submission
  - regardless of expiration date

693 currently approved protocols expire by 7/1/15
**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

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**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.

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**We’re here to help!**

- **Fridays 10:30-11:30**
  - Hammer 202A
  - April 24th
  - May 22nd

- **Mondays 3:30-4:30**
  - Hammer LL205
  - April 6th
  - May 4th

Additional times will be added.
Questions?

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– 212-851-7040

HRPO Staff:
http://www.cumc.columbia.edu/dept/irb/documents/I
RBStaffDirectoryexternal9.15.2014.pdf