IRB Update

Monthly IRB-Investigator Meeting
October 15, 2013

Brenda Ruotolo
Interim Executive Director
Columbia University IRB
What’s New?

• Relocation of IRB office
• Changes in IRB staffing
• New guidance documents
• Revised Policies
• Rascal enhancements
• Networking session 11/12/13
• Central IRBs
• Honest Brokers

What questions do you have?
We have moved!

154 Haven Avenue, First Floor (173rd St. and Haven)

SPA, IACUC – Second floor  CTO-Third floor

Revised CFs and/or Addenda needed
Staffing Changes

*Challace Pahlekan on leave; additional oversight by Laurence Butaud-Rebbaa
New Guidance Documents

• Processing of Reports of External Unanticipated Problems

• Reporting of Protocol Deviations and Violations
  • IRB SOPs to be revised; CRH has been updated

• Processing of and Checklist for IRB Authorization Agreements

• Processing of and Checklist for Individual Investigator Agreements
Revised Policies

• Noncompliance in Research Involving Human Subjects, effective July 31, 2013

• Data Security Policy, effective date TBD
Rascal Enhancements

- IRB Manager approval of administrative modifications – in effect
- Sort function on search results – in effect
- Approved closures no longer appear as expirations and emails no longer sent - in effect
- “Person obtaining consent” question – in effect
- Pop-up reminder for pdf, unsecured documents only – in effect
- Reminder to select ALL research procedures - in effect
- Suspension status – ETA next week
- Ability for IRB staff to pre-select docs to be stamped – ETA next week
Networking Session 11/12/13

Objective: Promote sharing of Best Practices

• What works for you?
• Bring your templates and tips to share!

*Room Hammer LL204
4:00-5:00 pm
*Subject to change – listserv email will be sent when this is confirmed
Tools that Increase Efficiency/Quality

• Templates - consent, correspondence, protocol
• Educational and training sessions - didactic and hands-on
• Website
• Listserv
• Drop-in consultation hours
• Interaction with Rascal programmers
• Staff training
• QA/QI, analysis of metrics
Central IRBs

- Requests for use increasing
  - Grant recommendation or requirement
  - Emphasized in ANPRM for 45 CFR 46
- Objectives
  - Shorter initiation period
  - Reduced burden of IRB review
- Present Models
  - What they can or are doing
  - What they cannot and are not doing
  - Distinction between regulatory and institutional requirements
- Guidance being developed
Honest Broker systems

• Objectives
  • Make specimens/data “not readily identifiable” therefore NHS per 45 CFR 46
  • Important exception: medical device testing 21 CFR 812
    • Definition of human subject includes specimens

• Current Status
  • Under review
  • Scope is broader than the IRB
Reminders:

- IRB members needed (Wed. 3pm meetings)
- Brochures for potential study participants
- Minimal Risk templates
- Data Collection worksheet
- Consent process worksheet
- Bookmark the IRB website for easy reference
**Columbia University Human Research Protection Program (HRPP)**

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<th>Regulations</th>
<th>Policies &amp; Guidance</th>
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<td>Selected University Research Policies</td>
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<td>State Law</td>
<td>IRB Policies/Procedures/Guidance</td>
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<td>General: OHRP &amp; FDA</td>
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<td>Related Information</td>
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**Ethical Principles**

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<th>Education &amp; Training</th>
<th>Required Training:</th>
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<td>Human Subjects Protection</td>
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<td>HIPAA (for Research)</td>
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<td>Research with Minors</td>
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**Additional Training Opportunities:**

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<th>Monthly Investigator Meetings</th>
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<td>IRB 101</td>
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<td>Annual Educational Conference</td>
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<td>Other Web-Based Training</td>
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**Frequently Asked Questions**

**Related Links**

- [CU IRB (Morningside Campus)](http://www.cumc.columbia.edu/dept/irb/)

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**News & Announcements**

**IRB Office Administrative Hours Announced!**

The IRB Office has implemented "Administrative Quiet Time" every day from 11:00am to 1:00pm. The IRB Staff will not be responding to email or phone calls during that time. If you have an emergency during these hours, please call the IRB Office Main Line at (212) 305-5883.

**Current list of CUMC IT certified systems:**

[https://secure.cumc.columbia.edu/cumcit/secure/security/scp_systems.html](https://secure.cumc.columbia.edu/cumcit/secure/security/scp_systems.html)

**4/3/2013**

**IRB 101**

- **Date:** April 23, 2013
- **Time:** 10:00am - 2:00pm
- **Location:** Alumni Auditorium (Black Building)

**4/9/2013**

**Monthly IRB - Researcher Meeting**

- **Date:** April 18, 2013
- **Time:** 3:30 - 4:30 pm
- **Location:** Amphitheatre 7, P&S 7th Floor

**Topic: IRB Updates**

Presented by: Brenda Ruotolo, Interim Executive Director, CU IRB

**RSVP:**

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**CUMC:** [http://www.cumc.columbia.edu/dept/irb/](http://www.cumc.columbia.edu/dept/irb/)
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