IRB Update
Part 2
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Presentation Topics

1. Incidental Findings Policy
2. Withdrawal of Subjects from FDA-regulated Trials
3. New Rascal stamping function
4. Minimal Risk Consent Form templates
5. Students as Researchers Policy and Guidance
6. Secure electronic environments
Documents from Sept. 20, 2012 MIM

Posted on CUMC IRB website, Policies and Guidance page:

- Investigational Devices
  - Device Studies: Important Information to Include in Submissions
  - Standard Operating Procedures for Medicare Approval of Device Trials
  - Instructions for NGS Submission to Request Coverage Decision
- IRB Review
  - Abbreviated IRB Submission for Multicenter Studies Sponsored by Industry or NIH Cooperative Groups
  - Additional Requirements for Protocols Funded by Specific Federal Agencies or Subject to Specific Federal Policies
  - IND/IDE Determinations: Roles of the IRB and IND/IDE Assistance Program
  - IRB Reviewer Form for Behavioral Research
  - IRB Reviewer Form for Medical Research
  - IRB Combining Review (Renewal) Reviewer Form
  - Research Protocol Format (for RASCAL Study Description)
  - Tips to Facilitate Efficient IRB Review - Protocols
  - IRB Fee Schedule
  - Decision Charts
    - NIH Private Info or Biological Specimens Decision Chart
- IRB Standard Operating Procedures Version 4, effective 6/12/2012
  - Table of Contents for IRB SOP Version 4, effective 6/12/2012
- Medicare Approval for Billing of Investigational Devices: Instructions for NGS Submission
- Standard Operating Procedure for Medicare Approval of Device Trials
- Noncompliance Policy
- Oral History Projects Policy
- Pathology Approval Form
- Pre-IRB Review Pediatric Human Subjects Checklist
- Research Involving Pregnant Women
  - Pregnant Women: Clinical Research Involving Pregnant Human Subjects
- Reimbursement / Compensation Policy
- Stem Cell FAQ (NINDS)
- Students as Researchers Policy and Guidance
- Students as Study Subjects in Research
- Tissues
  - Department of Pathology Approval Form
  - Guidance on Research Involving Coded Private Information or Biological Specimens
  - IRB Terminology Related to Tissue or Data Collection
  - NCI Best Practices for Biospecimen Resources
  - Repositories, Tissue Storage Activities, Data Banks, CHRP Guidance (Nov. 1997)
  - Review of Research Using Human Specimens
- Unanticipated Problems: Reporting to the IRB of Unanticipated Problems Involving Risks (replaces Adverse Event Reporting Policy)
  - FDA/NIH Safety Reporting Portal
  - Use of Publicly Available Datasets
  - Withdrawal of Subjects from FDA-Regulated Studies
Incidental Findings Policy

• Effective date: August 7, 2012
• Important Terms
  • IF Studies
  • Required Review Image
  • Credentialed Radiologist
  • Excepted Scan
  • IF of Clinical Significance
• Reporting of IF form
• Sample consent form language
Withdrawal from FDA-regulated Studies

- Effective date: September 10, 2012
- FDA Guidance: October 2008
  - FDA policy: data collected from subjects must be retained even if the subject voluntarily drops out
  - Appropriate informed consent for continued monitoring or follow-up procedures to which subject agrees
- Consent form language
New Rascal Stamping Function

- Release date: October 15, 2012
- Stamping by Rascal of study-related documents
  - After IRB approval
  - Documents must be in pdf format
  - Minimum margin of 1” at bottom of document
  - Stamp is translucent so underlying text is generally readable (for situations that will not support a 1” margin)
- Phase-in period
  - Initially: IRB staff will convert documents already submitted
  - Expectation: Submission of pdf documents by Nov. 15
- *Use of Rascal-generated consent forms is still recommended!!!*
8am-1:15pm in Low Library
1:30pm-4:15pm in Lerner Hall
Difference in Process: Rascal Stamping

CF Builder Stamp

New Stamping Feature

- Simultaneous
- Two-step process
Minimal Risk Consent Form Templates

- Release date: May 25, 2012
- Purpose: Facilitate creation of acceptable CFs
- Two templates:
  - Minimal risk
  - Minimal risk including audio- or video-recording
- Available on IRB websites
Students as Researchers Policy and Guidance

• Effective date: March 16, 2012
• IRB reviews research with human subjects
• Research: a systematic investigation designed to develop or contribute to generalizable knowledge
• Columbia requires submission of some student projects that do not meet the federal definition of research, in order to protect the subjects in such activities.
• IRB communication is with the PI
Student Projects Involving Human Subjects and NOT Requiring Submission

Student projects that are designed solely to provide students with an opportunity to learn or practice research methods do not require IRB review if they meet all of the following criteria:

(1) take place in a classroom, department, dormitory, or other campus setting, or in a public setting with generally unlimited access to the public, such as a shopping center, park, or street;

(2) involve only the learning of research techniques and are not designed to potentially advance the literature;

(3) involve no more than minimal risk to subjects (Minimal risk is defined as the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests); and

(4) utilize anonymous collection of data (i.e., with no names, social security numbers, or other direct identifiers; and without codes that can be linked to a list of names; and including no indirect identifiers or information that when combined would allow identification of the subject).

Research conducted over the internet will not be permitted under this category.
Secure Environments for Electronic Data

• Policies under development (*confidentiality including electronic data, standalone electronic data*)

• Need to protect PHI and PII (*electronic and other*)
  – Data plan in IRB submission
  – What, where, who

• IT-Certified environments for electronic data
  – Includes CUMC IT servers
  – Basis: IT policy for registration and certification of multi-user systems
    • Expansion to potentially cover:
      – Single-user systems
      – Certification of systems storing PII
Summary

• New policies and guidance
• Rascal enhancement
• Development of data security policy
• Refer to IRB websites frequently
• Utilize tools provided by IRB and Rascal
Questions?

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