Central IRBs

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Columbia Education Day Workshop #B2
Roone Arledge Auditorium
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Objectives

• Explain why and who benefits from the centralized IRB models

• Identify existing models of central IRB review

• Determine the resources required

• Share two models: FHCRC lead IRB process, followed by IRBshare staff presentation
Upon completing this workshop, participants will be able to:

• Identify regulatory guidance supporting IRB reliance arrangements

• Understand who benefits from centralized IRB processes

• Formulate effective management strategies serving as the IRB of record; or, relying upon another IRB
Regulatory Guidance Permitting IRB Reliance

- Federally funded research 45 CFR 46.114
- FDA regulated research 21 CFR 56.114


- Pending FDA/OHRP Harmonization guidances (per Kristina Borror, OHRP at AAHRPP Conference April 25, 2014)
  
  *Joint Draft Guidance on Exculpatory Language*
  
  *Transferring From One IRB to Another IRB*
  
  *IRB Written Procedures*
~110 assured institutions rely on FHCRC as the IRB of record for one or more protocols
FHCRC IRB relies on 13 registered IRBs for review

- One Independent IRB
- Cooperative review agreements with six local institutions
- NCI CIRB
- Others as requested by FHCRC PI
Requirements – More Work for IRB Staff Coordinating Lead IRB

• Infrastructure changes:
  – Programming
  – Filing system
  – Protocol level versus site level records

• Education of the IRB on how to be a Lead IRB

• Local consulting reviewers to satisfy OHRP guidance *IRB knowledge of local research context*

• IRB authorization agreements with each institution to defer IRB oversight
Benefits (from regulatory staff perspective)

- **Better control of the consent forms.** We kept them fairly uniform and at 8th grade reading level or below.

- **Efficiency**

- **Gratitude by site staff.** Some staff members felt relieved to be out of preparing an IRB application. They welcomed us doing it and were grateful.
Resources required to either serve as Central IRB or rely upon another registered IRB

When relying on an external IRB:

An institution relying on one or more IRBs still require staff time to organize institutional responsibilities other than IRB review.

When serving as a central IRB for one or more sites:

Requires considerable IRB staff coordination with off site institutions (Auth. Agreements, local reviewer, communications when reporting outside to OHRP/FDA, etc.)
Relevant FHCRC IRB policies/procedures:

- Multi-Center Study Coordination (Policy 2.14)
- Continuing Review (Policy 2.2)
- Closure and Re-open (Policy 2.9)
- Federalwide Assurance (Policy 1.2)
- Special Form: Local Context Review form

All forms and procedures can be found on the FHCRC-IRO extranet site http://extranet.fhcrc.org/EN/sections/iro/irb/
Other resources

  
  Article entitled “New Models for IRB Review Emerging to Address Changing Needs”

- **Advanced Notice of Proposed Rulemaking (ANPRM)**
  
  
  Notice of Proposed Rulemaking *(NPRM)* not released yet (as of 4/30/14). ANPRM strongly suggesting/encouraging centralized IRB models
Other Examples: Central IRB Models

• NeuroNEXT
  (PRIMR webinar entitled *Central IRBs: Models, Logistics and Implications* www.primr.org)

• Commercial/Independent IRBs
  (for more information see http://www.consortiumofirb.org/)

• NCI CIRB (https://ncicirb.org/cirb/default.action)

• IRBshare - Emily Sheffer presenting!