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Strategies to Support Cooperation of Multiple Organizations' Institutional Review Boards (IRBs)

Presented By:

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Abt Associates

Sponsored by the AHRQ PBRN Resource Center
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Agenda

- Welcome and introductions
- Presentations
  - Brief Q&A session following the first 3 presentations
- Q&A session with all presenters
- Instructions for obtaining CME credits

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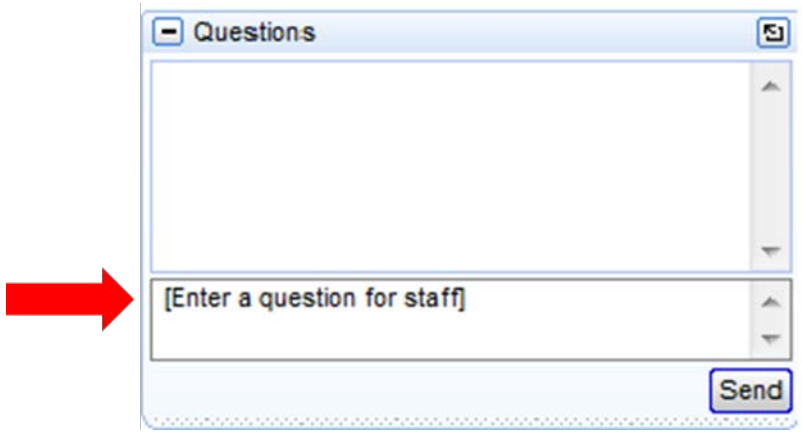


Today's Presenters

Research Collaboration with the University of Iowa

Jeanette M. Daly, RN, PhD
Associate Director
Iowa Research Network (IRENE)

Today's Presenters

University of Colorado Denver- COMIRB and the INSTTEPP Study

Tabria Winer, MPH
Coordinator
Shared Network of Collaborative Ambulatory Practices & Partners (SNOCAP)

Today's Presenters

Oregon Health & Science University Research Integrity Office: Ceding oversight across multiple IRBs

LeAnn Michaels
Manager
Oregon Rural Practice-based Research Network
(ORPRN)

Today's Presenters

The Collaborative Ohio Inquiry Network (COIN) & the Ohio Reliant IRB System

Amanda Ross
Administrative Director
Collaborative Ohio Inquiry Network (COIN)

Research Collaboration With the University of Iowa

"I SHOULD LIKE TO KNOW ABOUT RISKS… OUT OF POCKET EXPENSES…

TIME REQUIRED AND REMUNERATION… AND SO FORTH –

BY WHICH HE MEANT: WHAT AM I GOING TO GET OUT OF IT?

AND, AM I GOING TO COME BACK ALIVE?"

J.R.R. Tolkien, *The Hobbit*, Ch.1

All human subjects research conducted at the UI (or under its auspices) must be *reviewed and approved* by an

Institutional Review Board (IRB)

prior to the start of the research.

This includes cooperative research.

Cooperative Research

US DHHS and FDA provide federal regulations [21 CFR 56.114 & 45 CFR 46.114] that allow for cooperative research projects which involve more than one institution as multiple IRB applications would be redundant.

Cooperative Research

Minimally involves one practice-based research network (PBRN) at an academic center with multiple family physician offices who may or may not have their own IRB.

Community-based research often involves collaboration with non-UI entities, whom we call community partners

Community partners generally fall into two basic groups:

Those who have their own IRBs, and those who don’t

The University of Iowa

The purpose of our community-based research program is to facilitate community-based research by providing mechanisms to extend UI IRB oversight to community partners

Collaborative research is considered community-based research when:

1) The project meets the federal definition of "<u>research"</u>

a systematic investigation including research development, testing and evaluation, designed to develop or contribute to *generalizable knowledge*

2) The research participants are <u>"human subjects"</u>

***living* individuals about whom identifiable private information is obtained or data is obtained through an intervention or interaction**

3) The community partners are <u>"engaged"</u> in the research

***actively* obtaining data as above, or obtaining informed consent of the research subjects.**

4) The project is no more than "<u>minimal or moderate risk"</u>

risk is defined as the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation. Both the probability and magnitude may vary from minimal to significant

UI IRB oversight is extended to cover a community partner through…

An Individual Investigator Agreement (IIA)

Research collaboration with the University of Iowa

Human Subjects Office/IRB

Community Based Research

COMMUNITY PARTNER CHECK LIST

December 2012

EACH COMMUNITY PARTNER (CP):

- ☐ **Letter of Agreement** – submitted to the UI PI confirming, in detail, the CPs understanding of and role in the project.
- ☐ **Human Subjects Protection Training** certification for all "engaged" CP staff submitted to HSO
- ☐ **HIPAA letter** - from the CPs Privacy Officer (if project involves protected health information-PHI)
- ☐ **FERPA** training for all "engaged" CP staff (if project involves educational records)

Community Partners *without* FWAs or IRBs:

- ☐ **Individual Investigator Agreement** for an Individual (IIA-I); or Organization (IIA-O)
  - i. CP agrees to conduct the project in accordance with the UI's FWA
  - ii. CP acknowledges the UI as their IRB of record
  - iii. CP acknowledges the Human Subjects and FERPA educational requirements

Community Partners *with* FWAs but without IRBs:

- ☐ **FWA** provided to PI (even if not funded)
- ☐ **IRB Authorization Agreement** (IAA)
  - i. CP accepts and acknowledges the UI IRB as their IRB of record
  - ii. CP acknowledges the Human Subjects and FERPA educational requirements

The "Letter of Agreement" confirms:

1. That the community partner is committed to participating in the research.

2. That the community partner understands their role in the research.

3. That a collaborating site will allow conduct of the research on their premises and/or using their information and/or resources.

Organizations serving as community partners affirm that they will *maintain copies of all professional licenses and verification of background checks* on all staff members.

For independent community partners, "Letters of Agreement" are required from each organization on whose premises the research will be conducted and/or whose resources or information will be accessed. Individuals serving as community partners are asked to provide a copy of their *current CV or Résumé* to the UI Principal Investigator.

Human Subjects Protection Training

All community partner staff deemed to be “engaged” in research are required to complete Human Subjects Protection training.

An online course, Certification in Human Subjects Protections (CITI) is required https://www.citiprogram.org/

HIPAA

If a community-based research project will access *protected health information (PHI),* the Privacy Officer of the organization where PHI will be collected will need to provide written authorization

Sample IRB AA

If institutions have an FWA

Version Date: 03/31/2011

Sample text for an Institution with a Federalwide Assurance (FWA) to rely on the IRB/IEC of another institution (institutions may use this sample as a guide to develop their own agreement).

Institutional Review Board (IRB) Authorization Agreement

Name of Institution or Organization Providing IRB Review (Institution/Organization A):

_____

IRB Registration #: _____ Federalwide Assurance (FWA) #, if any: _____

Name of Institution Relying on the Designated IRB (Institution B):

_____

FWA #: _____

The Officials signing below agree that _____ may rely on the designated IRB for review and continuing oversight of its human subjects research described below: (*check one*)

(___) This agreement applies to all human subjects research covered by Institution B's FWA.

(___) This agreement is limited to the following specific protocol(s):

Name of Research Project: _____
Name of Principal Investigator: _____
Sponsor or Funding Agency: _____ Award Number, if any: _____

(___) Other (*describe*): _____

The review performed by the designated IRB will meet the human subject protection requirements of Institution B's OHRP-approved FWA. The IRB at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (Institution/Organization A):
_____ Date: _____

Print Full Name: _____ Institutional Title: _____

NOTE: The IRB of Institution A may need to be designated on the OHRP-approved FWA for Institution B.

Signature of Signatory Official (Institution B):
_____ Date: _____

Print Full Name: _____ Institutional Title: _____

IRB Ceding Process

- Gives control of IRB review, approval and oversight of human subjects research to another IRB
- Allows one IRB to rely on another IRB
- Reduces duplication of effort
- Increases efficiency by designating a single IRB

Polling Question

For more information contact:

Jeanette Daly, RN, PhD
Associate Research Scientist
Department of Family Medicine
University of Iowa
Phone: (319) 384-8995
jeanette-daly@uiowa.edu

Polling Question:

Does the IRB at your institution have ceding forms?

Various Types of IRB Cooperation In Support of Practice-Based Research

University of Colorado Denver- COMIRB and the INSTTEPP Study

Tabria Winer, MPH

COMIRB Background

- Colorado Multiple Institutional Review Board
- Affiliated sites include:
  - University of Colorado Denver (Anschutz and Downtown Campuses)
  - Denver Health and Hospital Authority
  - University of Colorado Hospital
  - Veteran’s Administration Hospital
  - Children's Hospital Colorado

COMIRB Background

- Comprised of five IRB panels
  - 4 review protocols for UCD and its affiliates and biomedical protocols
  - 1 reviews social and behavioral protocols
  - Adult and pediatric
- Ensures that appropriate safeguards exist to protect rights and welfare of research subjects

Conducting Practice Based Research In Colorado

- SNOCAP is the collaborative affiliation of practice based research networks in Colorado
  - 4 Primary Care PBRNs, 1 Public Health PBRN
- Department of Family Medicine, UC Denver- Anschutz
- Practices are located throughout the state- may not have formal IRB affiliation
- Member practices are not research practices- do “research on the side”
- SNOCAP contract with Colorado Central Area Health Education Center (CCAHEC)
  - Established in 2007
  - FWA on behalf on these unaffiliated practices
  - CCAHEC provides required human subjects training to practices

Conducting Practice Based Research In Colorado

- Responsibilities of CCAHEC:
  - Require that each practice have at least 1 lead clinician and 1 research coordinator complete the Human Subjects training
  - Train all practice personnel on the research study and COMIRB policies
  - Develop project specific MOUs with each SNOCAP practice
  - Monitor the conduct of research- recruitment and consent of subjects
  - Provide the COMIRB with all data related to university research studies

Conducting Practice Based Research In Colorado

- Responsibilities of the University of Colorado
  - Management of projects
    - Conduct research within practices
  - Provider on-going support of research
  - House all records of research projects
  - Provide evaluation and quality control of studies

Collaboration with Non-Affiliated Sites

- Ceding/serving as the IRB of record
- On a case-by-case basis may choose to provide oversight or cede to other institutions
  - Formal agreement established
    - MOU or IAA
  - Each institution is responsible for safeguarding the rights and welfare of human subjects
  - Each institution must comply with federal regulations

Collaboration with Non-Affiliated Sites

- COMIRB ceding to outside IRB
  - Protocol packet is submitted to COMIRB
  - COMIRB Director and Principle Investigator determine if appropriate to cede and if another IRB is appropriate to use
  - Relationship is established with outside IRB and COMIRB adds IRB to FWA
  - IAA is signed by both institutions
  - IRB of record receives protocol packet submitted to COMIRB for final approval
  - Once final approval is received, COMIRB will keep a copy of all approval letters, approved documents and signed IAAs
  - COMIRB remains responsible for ensuring compliance with the outside IRB's determination

Collaboration with Non-Affiliated Sites

- COMIRB as IRB of record for multi-site studies
  - Principal investigator and COMIRB director determine if appropriate to be oversight IRB
  - IAA established between the IRBs before study can be approved/research can be conducted
  - Non affiliated sites must add COMIRB panels to its FWA
  - “Multi- site studies” study attachment submitted with COMIRB application
  - All approval letters are available to outside IRB as needed

The INSTTEPP Study

- Implementing Network Self-management Support Tools Through Engaging Patient and Practices
- Multi-Site Study- ORPRN, IRENE, SNOCAP, WREN
- Determine best way to implement elements of the AHRQ Self-Management Support Toolkit
- Study Design:
  - Stepped Wedge Study Design
  - Qualitative Comparative Analysis
- Method:
  - Boot Camp Translation
  - CS-PAM/Theory of Planned Behavior
  - PAM

The INSTTEPP Study

- 16 practices across 4 states
  - Small to medium sized primary care practices
  - Begun to implement PCMH principles
- 80 clinic staff participants
  - Preform care management functions
- 320 patient participants
  - Have at least 1 chronic illness
  - Targeted for care management

Collaboration for the INSTTEPP Study

- IRB Application submitted to COMIRB
  - IRB of record
  - Expedited review
  - Data housed at UC Denver
  - Study coordination at UC Denver
  - Data collected at 4 study sites
- IRB of record process
- IAAs signed and collected
  - Kept on file at both sites
- 3 non-affiliated sites added COMIRB panels to FWA
- COMIRB Approval received

Questions?

COMIRB- 303-724-1055

COMIRB@ucdenver.edu

Campus Mail Box F490 13001 E. 17th Place, Room N3214 Aurora, CO 80045

Polling Question:

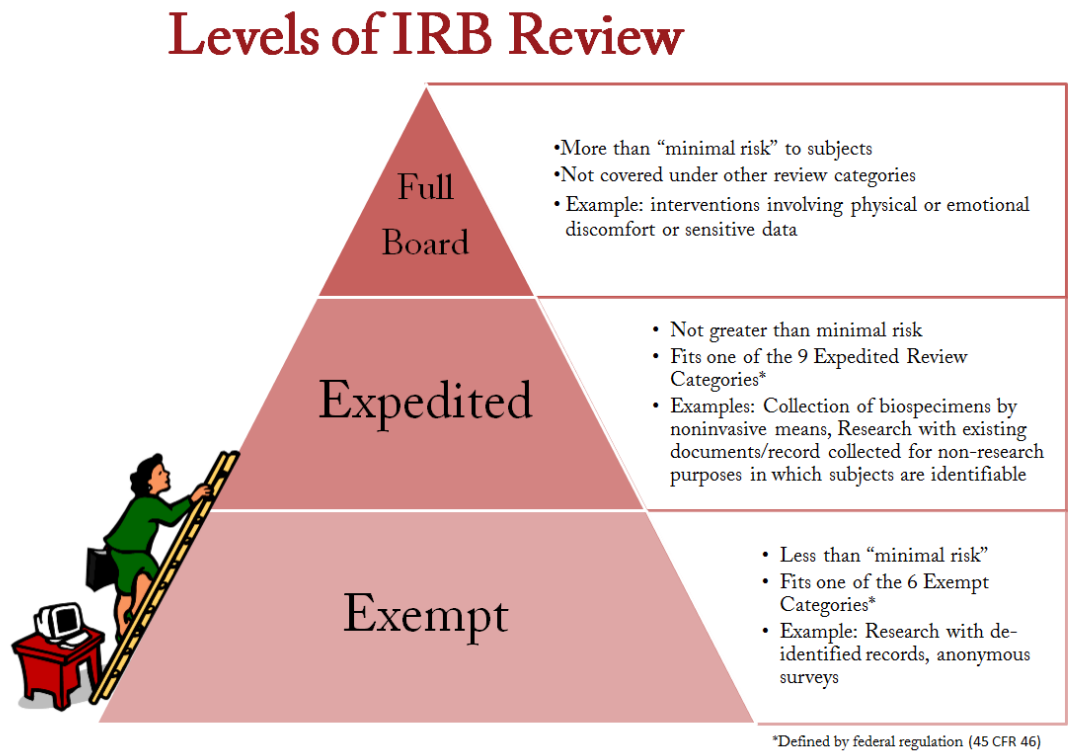
At your institution, what materials must be provided to cede to another institution's IRB?

Oregon Health & Science University Research Integrity Office: Ceding oversight across multiple IRBs

LeAnn Michaels, Manager
Oregon Rural Practice-based Research Network (ORPRN)
Meta-network Learning And Research Center (Meta-LARC)

Overview

- ORIO timeline for ceding oversight
  - Various health systems
  - Independent practices
- Meta-LARC goals and experience
- Lessons learned
- IRB Share



2002: Unaffiliated Investigator Agreement

- Investigators engaging in research at independent clinic or institution lacking FWA
  - Extends federal-wide assurance to cover collaborating <u>independent</u> or <u>institutional</u> individual investigator
  - Investigator completes human subjects training, conflict of interest and form
  - Submit modification
  - Takes 4-6 weeks to approve

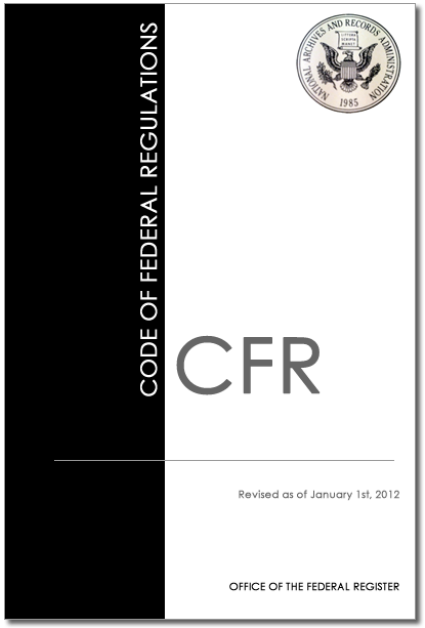
Waiver of Oversight 2009: Memorandum of understanding

- IRBs of regularly collaborating institutions agree to rapid approval to accept oversight
- Requested through new project submission
  - Memorandum of understanding (MOU)
  - IRB approval of overseeing IRB
- Process not used for full review projects
- Takes 2-3 weeks to approve

Waiver of Oversight 2011: IRB Authorization Agreement

- IRBs of smaller health systems not initiating research agree waive oversight
- Collaborating investigator submits letter requesting local (relying) IRB waives oversight
- Relying IRB signs IRB Authorization Agreement
- Modification + IAA submitted for approval
- Process takes 6-8 weeks

Independent Authorization Agreement OHSU accepts oversight



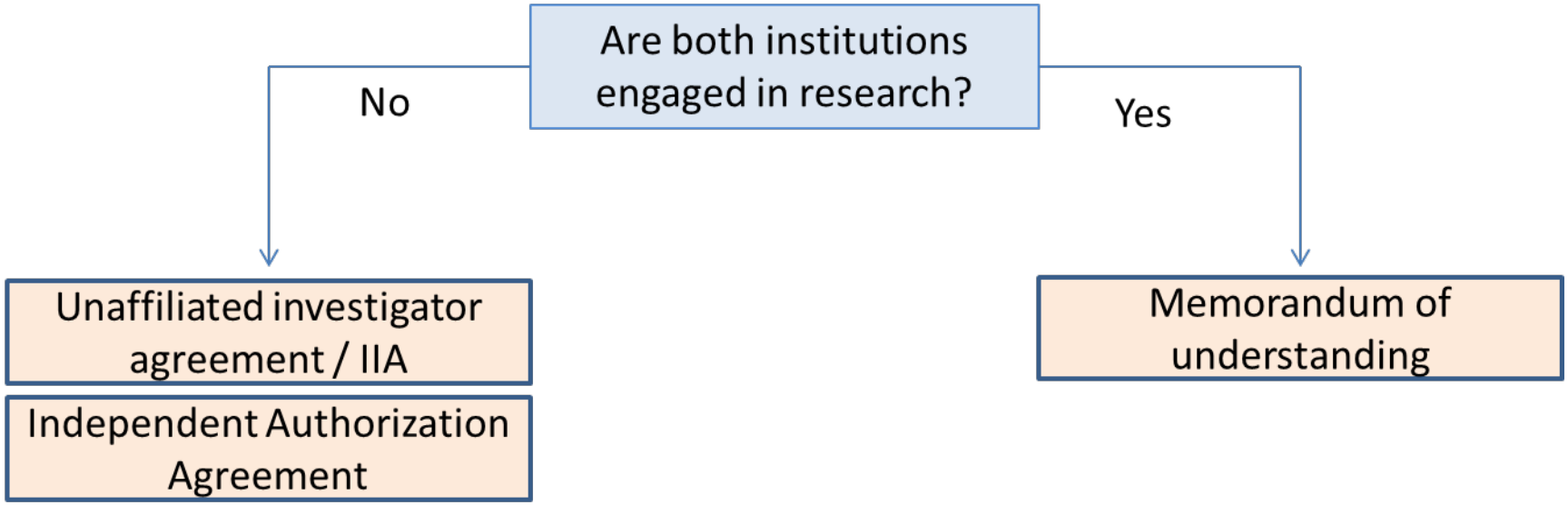
- Terms of authorization
  - Comply to laws outlined in the CFR
  - Both IRBs maintain FWA
  - Any (of 4) IRBs may review
  - Describes IRB review cycle
  - Relying institution will report unanticipated problems, protocol deviations, complaints, etc.
  - What relying institution must do (10 items)
    - Compliance, safe conduct, trained personnel, cooperate

Waiver of oversight

- In 2012, the OHSU IRB (ORIO) reviewed 659 new projects.
  - OHSU waiving oversight to another institution: 31
  - OHSU accepting oversight from another institution: Unknown

- Not huge demand … yet

Ceding oversight in two buckets

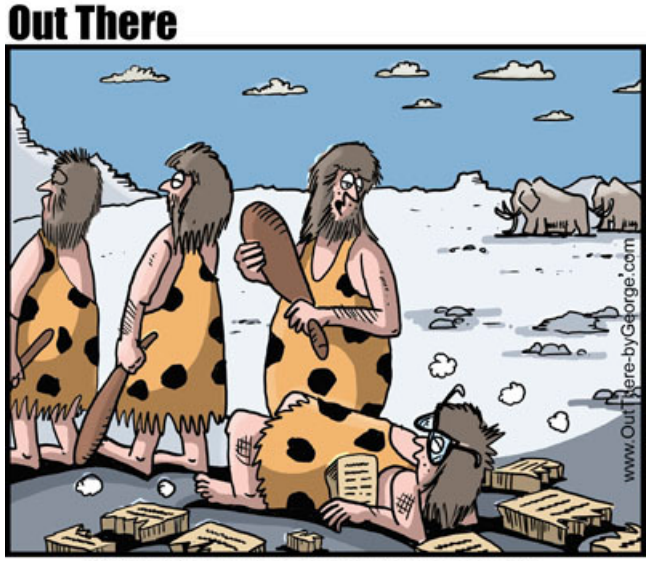


We are moving toward ceding oversight when both institutions are engaged in research – what does that look like?

2012 AHRQ P30: Meta-network Learning And Research Center

- AHRQ Centers for Primary Care Practice-Based Research and Learning emphasized nimble response using funded infrastructure
- Envisioned high level of IRB agreement and waiving oversight through MOU or rapid IAA, perhaps encouraged through CTSA
- We’re not there yet

Lessons learned:
IRB change is slow



"Let that be a valuable lesson for you...nobody likes a smart Neanderthal"

Lessons learned

- IRB reviews take time, no matter what
- Waiving/Ceding oversight can be more efficient (modifications) and increase safety (adverse events)
- It may not accelerate study start-up
- IRB chairs aren't necessarily in favor of doing this with greater frequency
- One waive, all waive can limit PBRN recruitment

2014: VA agreement

- Despite reluctance from Chair, 2014 brought new Joint submission agreement with Veterans Affairs Medical Center
  - Shared IRB that is separate board
  - Assumes equal/identical implementation of project
  - Separate tools (e.g. consent), but equivalent burden to subjects

IRB Share

45 institutions 11 projects

- IRBshare is a new joint IRB review model for multisite studies that facilitates the sharing of IRB-approved documents between IRBs, accelerates the IRB review process by enabling a temporary reliance between IRBs, and minimizes the need for all sites to conduct a full board review **— thereby helping to accelerate study start up.**

https://irbshare.org/#what

Polling Question:

Does your institution use IRBShare?

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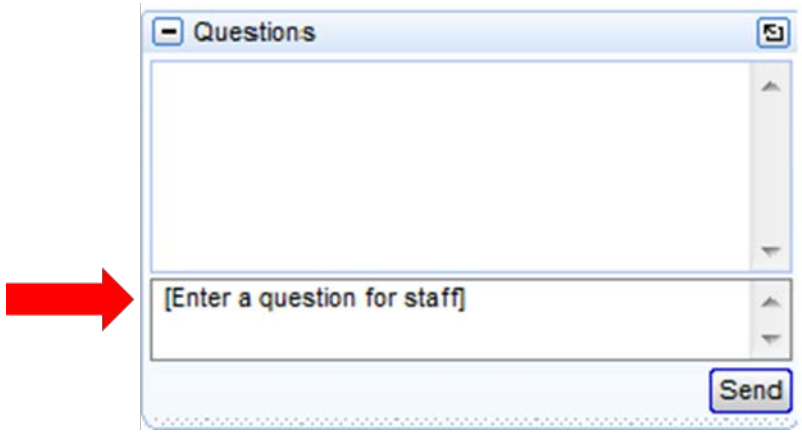

The Collaborative Ohio Inquiry Network (COIN) & The Ohio Reliant IRB System

9/10/2014

Amanda Ross
Administrative Director, PBRN Shared Resource
Collaborative Ohio Inquiry Network (COIN)

SCHOOL OF MEDICINE
CASE WESTERN RESERVE UNIVERSITY

Collaborative Ohio Inquiry Network

PRACTICE BASED RESEARCH NETWORK LEARNING COMMUNITY

The Collaborative Ohio Inquiry Network (COIN) is a PBRN learning community that develops the capacity of PBRNs for research, conducts high-impact practice-based research, and translates research into practice.

COIN is an AHRQ Center for Primary Care Practice-Based Research and Learning - P30 HS021648

Ohio CTSAs provide a backbone for collaboration

COIN's 9 PBRNs are affiliated with 4 academic health centers, 3 of which have **Clinical and Translational Science Awards (CTSAs)** that support practice-based research in their 8 affiliated networks.

History of IRB collaboration in Cleveland

Initially, Cleveland Institutional Review Board (IRB) administrators and institutional officials used *Inter-Institutional Authorization Agreements* in order to be able to “rely” on the review and oversight of a main IRB

Initial Collaborating Cleveland institutions

- University Hospitals Case Medical Center, MetroHealth Medical Center, and Case Western Reserve University
  - Cleveland Clinic joined in 2005

Caveats

- Case Western Reserve University (CWRU) does not have a Biomedical IRB so they cannot be “relied upon”
  - CWRU investigators were/are referred to one of the affiliate Biomedical IRBs if reliance is desired
- Cleveland Veterans Administration (VA) cannot participate
  - VA IRB must review all projects

Evolution of IRB collaboration in Ohio

V 1.0 – Cleveland's "Facilitated Review" Process (2010)

- Leveraged **the MetroHealth electronic IRB platform**
- Each institution used it's own forms – consent forms, etc.
- Each institution performed a FULL local review for context and to approve data use agreements

Evolution of IRB collaboration in Ohio

Meeting of the Ohio CTSA Institutional Review Board (IRB) Administrators (2012)

8 participating IRBs

- Case Western Reserve University
- MetroHealth Medical Center
- University Hospitals Case Medical Center
- Cleveland Clinic
- Ohio State University
- Nationwide Children's Hospital
- University of Cincinnati
- Cincinnati Children's Medical Center

Evolution of IRB collaboration in Ohio

V 2.0 - "Reliance Agreement" across the 3 Ohio CTSAs

- Electronic IRB HUB is created – leveraged MetroHealth system
- ***IRBs no longer complete local reviews***
  - Two page electronic application to be <u>completed by the administrator for IRB of Record</u>
  - System of review for "relying" IRBs regarding DUAs
- The only "decision" of the relying IRB is whether or not to rely on the IRB of Record

Goals & Benefits of Reliant Review

- Decrease burden on investigators while maintaining integrity of IRB review
- Streamline multi-center research and grow collaborative research across Ohio
- Create a transparent and accessible electronic IRB process

Key elements of Reliant Review

- A brief request form
- A single IRB submission to the IRB of record
  - Initial submission or amendment to a protocol within the IRB of Record
- Electronic HUB with all study documents and reviews from IRB of record, facilitated by IRB administrators
- Online review by all named IRB(s) with the ability to request additional site specific information

Preparing for a Reliant Review: A checklist

- ❑ Collaborative protocol – initial submission or amendment
- ❑ IRB of Record
- ❑ Communication with home (relying) IRB regarding the Reliant Review process
- ❑ Register ALL collaborating researchers and staff from collaborating institutions within the MetroHealth Electronic IRB system

The *IRB of Record's* Reliant HUB Responsibilities

- Coordinate the submission of protocol into the HUB
  - Complete brief request form
  - Upload complete approved protocol, including all attachments, consent documents, required regulatory determinations, approval notices and IRB communications
- Communicate with relying IRBs to confirm collaboration

Role of the Relying IRB (RIRB)

- Agree to review the protocol
- Conduct an Institutional Requirements Review of the application submitted into the HUB

➢ **The only changes allowed are to the consent forms and include the addition of language pertaining to persons to contact at the RIRB organization with questions and concerns, and subject injury language**

Role of the Relying IRB (RIRB)

- Approve (or disapprove) the protocol for local implementation
  - Issue an approval letter (or denial)
  - Record the date the Reliant Review was approved (or denied) at RIRB organization
  - If approved, place the approved consent language on their template and stamp it.

Continuing Reviews, Amendments, etc.

- Communication across collaborating study staff and IRBs is key
- Coordinated by the IRB of Record
- Uploaded into the IRB HUB for review by all “relying” IRBs
- RIRBs can complete administrative actions within the HUB, including adding documents of local significance, amending study staff or closing the local study site

Ongoing collaboration and growth

- 65-70 studies exist within the Ohio Reliant Review HUB
- The Ohio Reliant Review HUB is reviewed and refined on a regular basis to increase the opportunities for streamlined collaboration

COIN and the Ohio Reliant IRB System

- Case Western Reserve University, The Ohio State University and The University of Cincinnati, and their participating healthcare institutions, all have representation within the Ohio Reliant Review System

- The Northeast Ohio Medical University, the 4th COIN partner, does not have representation but has agreed to "independently rely" on the appropriate IRB of Record for COIN projects on a case by case basis

Acknowledgements

COIN Partners at OSU, UC, NEOMED

Kathy Lawry, MSSA, CIP, LISW
Director, Reliant Review, MetroHealth System

Questions, Comments?

Amanda Ross

ajr67@case.edu

Polling Question:

Would you be interested in accessing and expanding reliant-IRB in your local area?

How to Submit a Question

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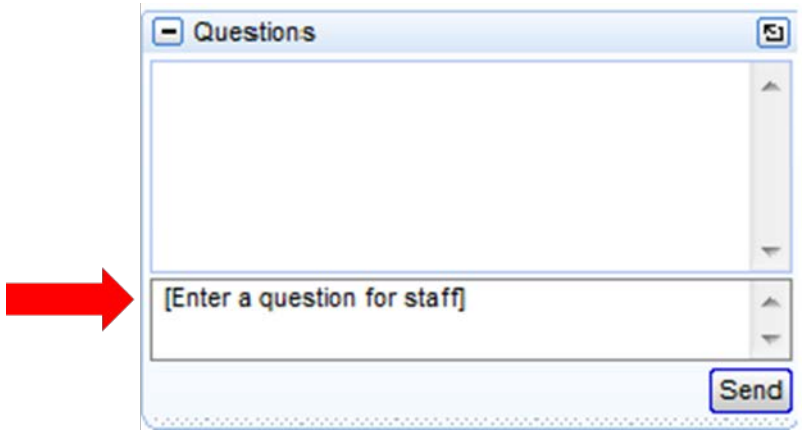

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- **September 30, 2 – 3:30pm ET:** September 30 PBRN Webinar on PBRN Research Good Practices (PRGPs) Report

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