

Research Institution Perspectives on Advancing the Use of Central IRBs for Multicenter Clinical Trials in the United States

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6th February, 2014

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Streamlining Oversight for Multisite Research: Results of a Randomized, Controlled Trial of Central Versus Local IRB Review

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Presentation for Clinical Trials Transformation Initiative (CTTI) Webinar

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Background: What is the problem?

- Oversight system has not evolved to keep pace with volume, complexity and nature of research it oversees
 - Predicated on local review of single sites
- Multi-center research is essentially a *take-it-or-leave-it proposition* for individual sites
 - Fundamental premise → identical protocol conducted identically across all sites
 - Local IRBs are left “tinkering around the edges” with the things they can control (consent forms, etc)
- Net result → Ineffective oversight of study-wide issues by patchwork quilt of independent sites
 - Change has begun to occur → AE reporting

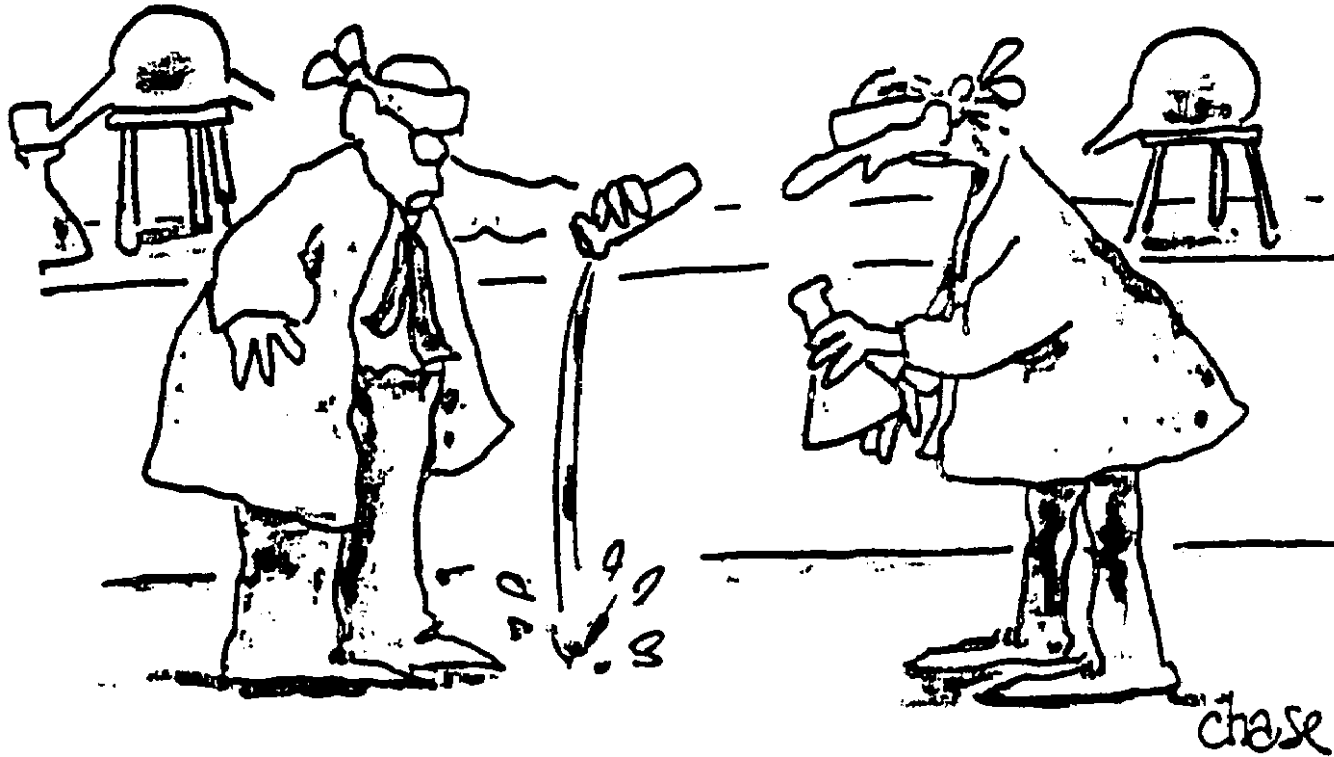
Background: What are the solutions?

- Proposed changes to the regulations (federal ANPRM) would mandate single IRB review for multisite studies
- Institutions have been exploring alternative models
 - Typical model involves contracting with single external IRB for outsourcing of industry-sponsored protocols
 - This “sole provider model” has its own problems → trades one IRB for one IRB
- UNC already relies on external IRB for 300 studies/yr
- We are considering a policy change that would address these shortcomings

Methods: Central IRB Pilot Project

- Aims:
 - To test a model that allows reliance on *any central IRB already involved with a multicenter clinical trial*, provided certain criteria are met
 - To gather data and experience to support an informed policy decision at our university
- Pilot period: July – December 2012
- Sample: 43 consecutive industry-sponsored multi-site clinical trials
- Study design: Controlled, randomized, blinded

DOUBLE BLIND STUDY



UNC Investigators, IRB members and IRB staff were all blinded to status of individual studies in the pilot project

Methods: Review and Randomization

- All studies first reviewed by UNC Biomedical IRB(s) → then randomized 1:1
 - Control
 - Remained under UNC review
 - Experimental
 - Investigators given permission/instructions to register with central IRB for that study
 - Only stipulation = notify UNC when registration/approval is complete
 - UNC contingencies archived for analysis
 - With “escape hatch” mechanism to immediately review reasons for any deferrals or disapprovals

Methods: Central/Independent IRBs

- Eligibility
 - AAHRPP accredited
 - In good standing with OHRP and FDA (e.g., no outstanding issues or Warning Letters)
 - Willingness to establish Master Service Agreement with UNC

Methods: Data Collected

- Potential impact on local IRB workload
- Administrative issues dealing with multiple central IRBs
- Researcher Satisfaction and Feedback
- Turnaround time (both local and external)
- Contingencies identified by local IRB on studies already reviewed/approved by central IRBs → Quality Control

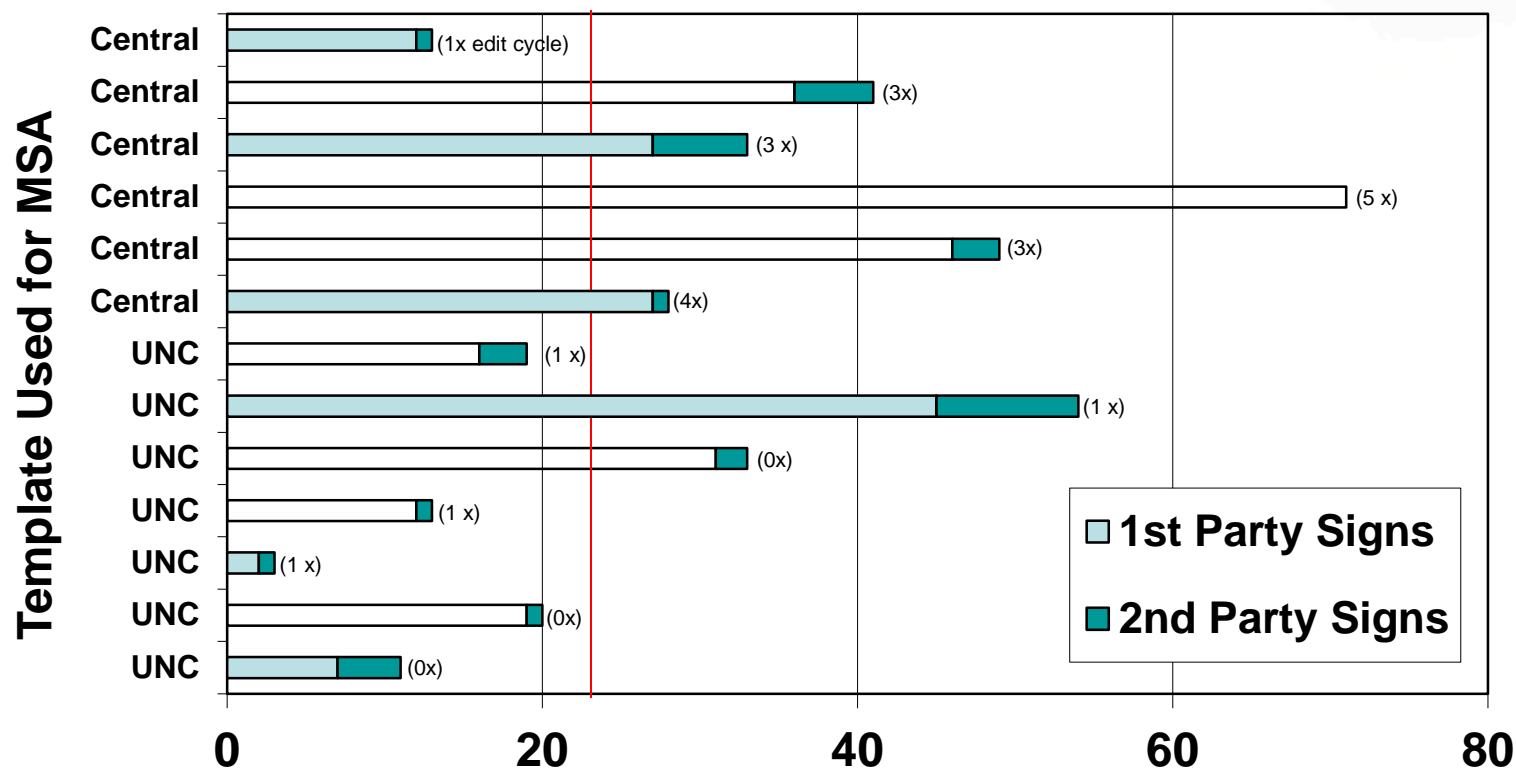
Central/Independent IRBs Eligible for Inclusion in Pilot

20 eligible IRBs → 13 executed agreements → 8 ultimately used in pilot

- Alpha IRB
- ✓ Aspire IRB
- BRANY
- ✓ Chesapeake IRB
- ✓ Compass IRB
- ✓ Copernicus IRB
- Ethical & Independent IRB
- Goodwyn IRB
- Harrison IRB
- IntegReview IRB
- IRB Company
- IRB Service, LTD
- Liberty IRB
- Midlands
- New England IRB
- ✓ Quorum IRB
- RCRC IRB
- ✓ Schulman and Associates
- ✓ Sterling
- ✓ WIRB

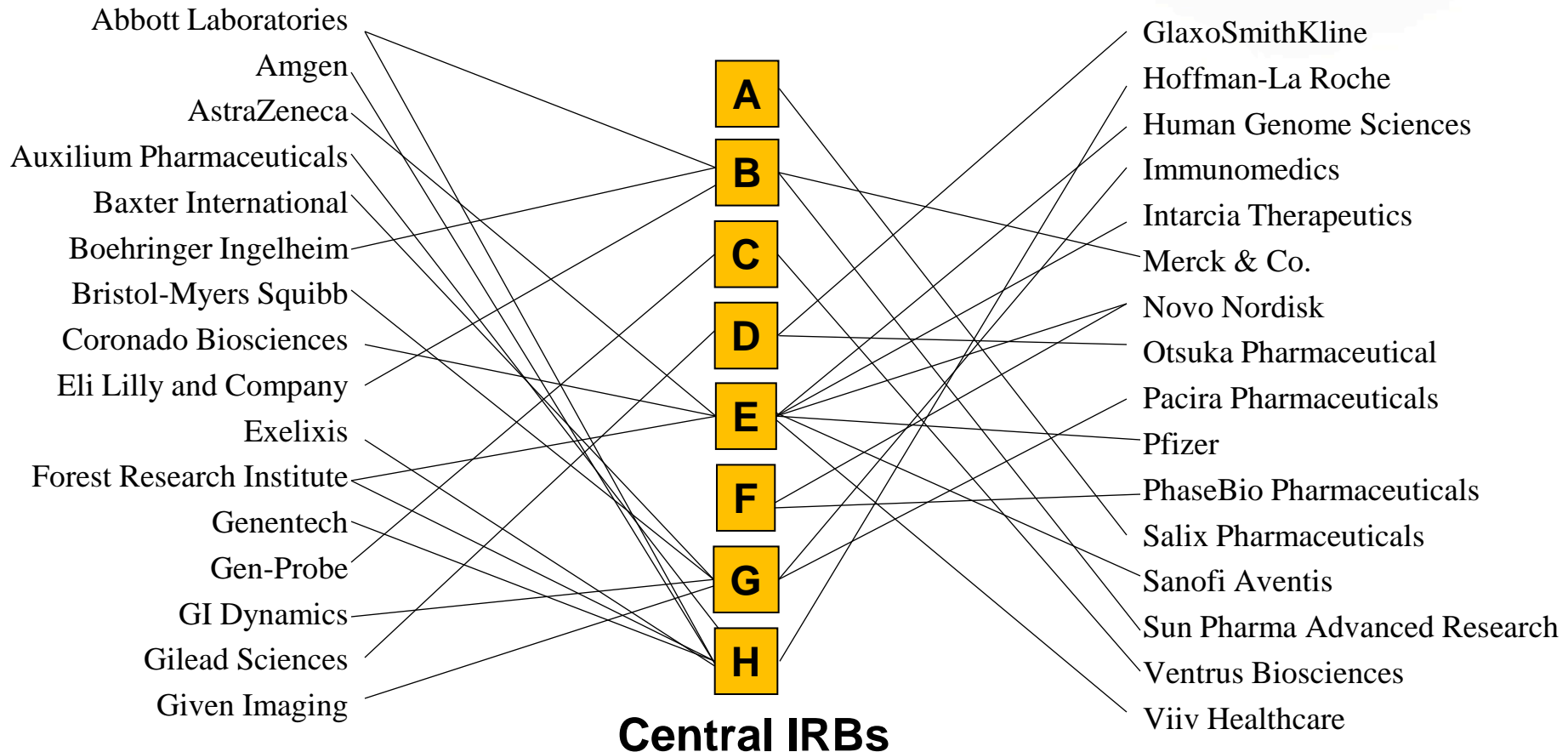
Note: utilization of eligible IRBs was entirely dependent on which IRB had reviewed a given study being opened at UNC

Days to Execute Master Service Agreements with Central IRBs (N=13 of 20)

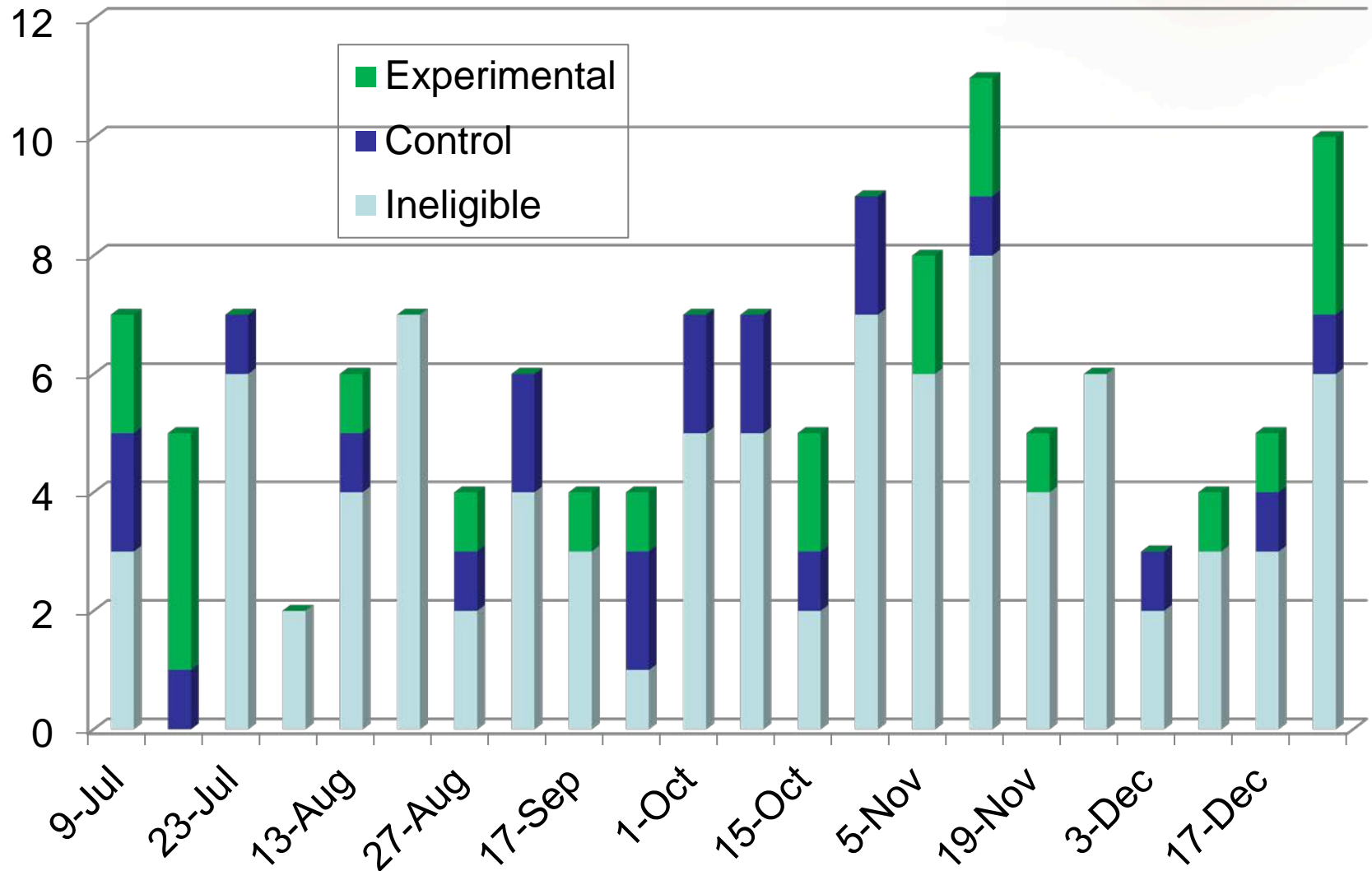


Note: 6 of 13 IRBs used their own templates, 7 of 13 used UNC template

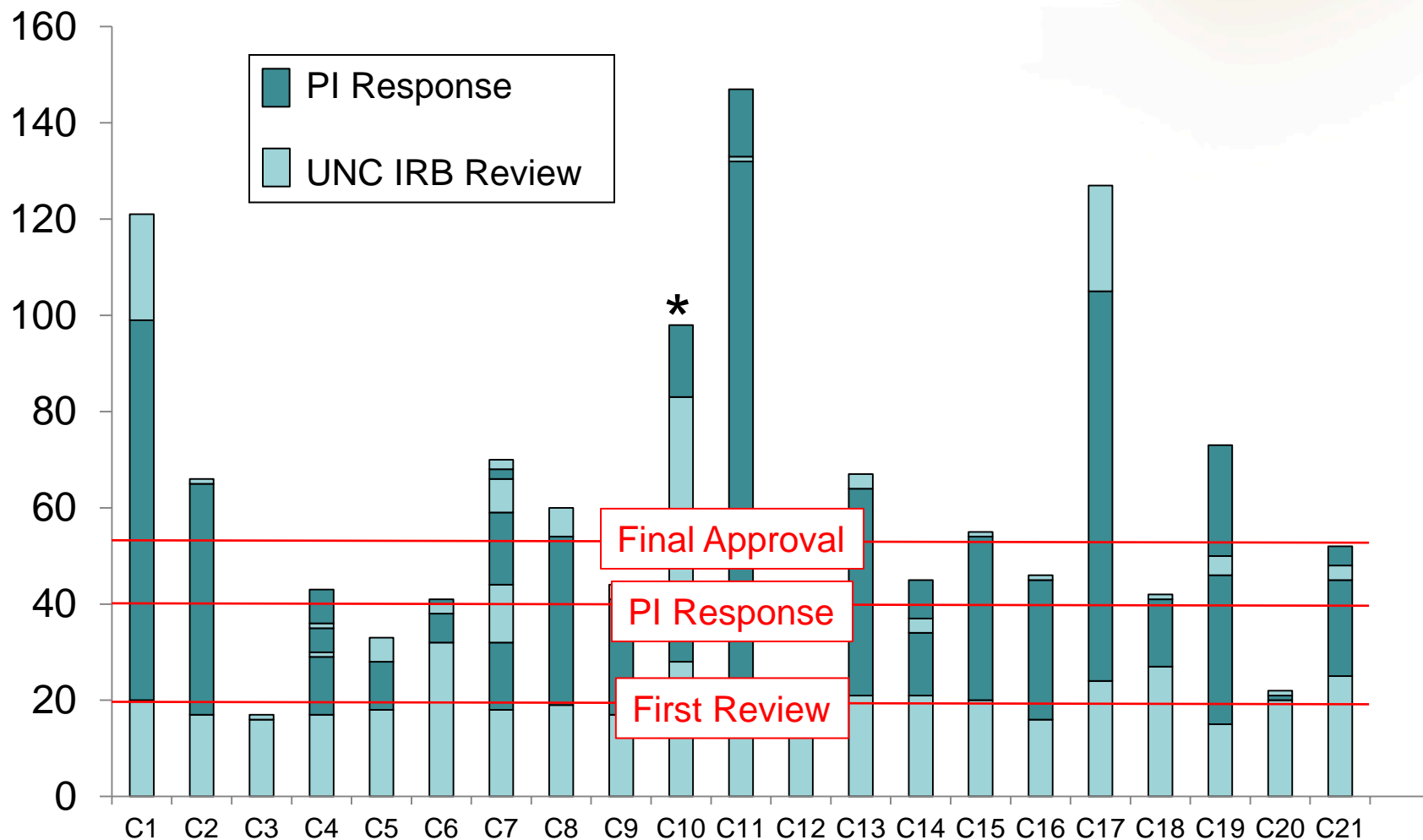
43 Studies : 32 Sponsors : 8 Central IRBs



Randomization of Eligible Trials by Weekly Meeting

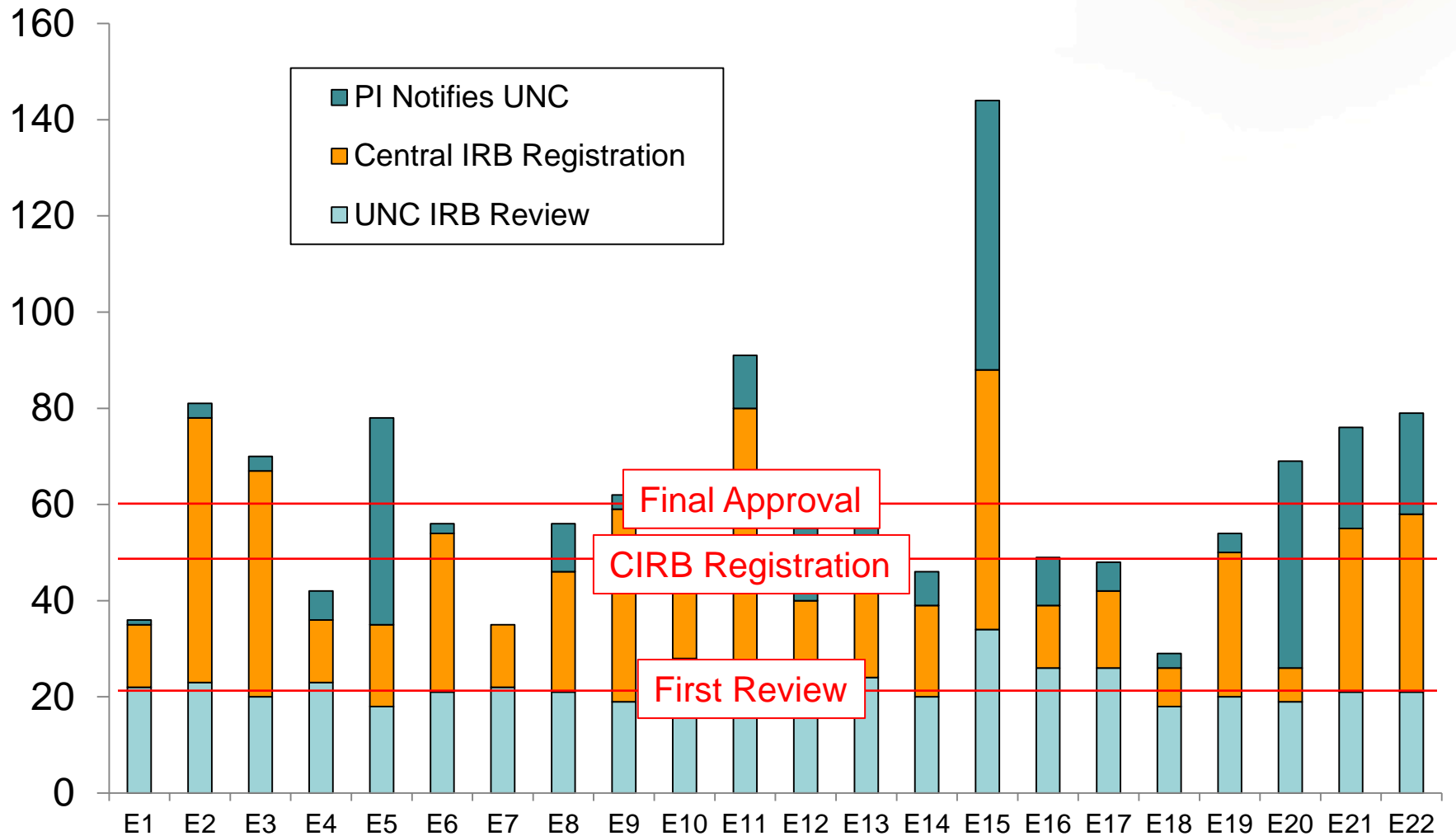


IRB Turnaround Time in Days from Submission: Control Studies (N=21)



* Originally randomized to external IRB, converted to control after “escape hatch” review

IRB Turnaround Time in Days from Submission: Experimental Studies (N=22)



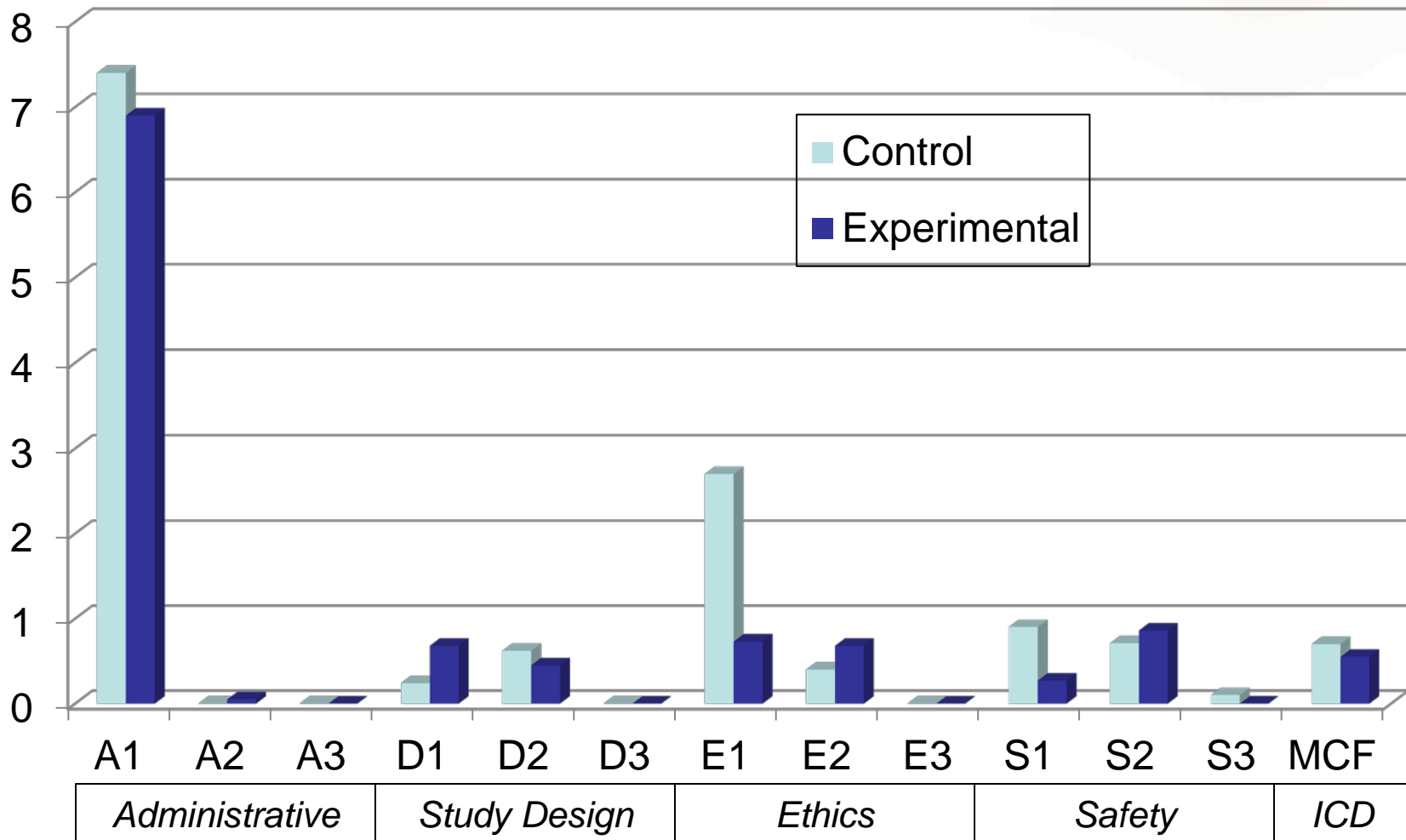
* Referred to "escape hatch" review, remained with external IRB

Comparison of Respective Components in Terms of Processing Time (median no. days)

	Control (N=21)	Experimental (N=22)	
UNC IRB Review	20	(20)	
Initial PI Response	20	---	
Central IRB Registration	---	27	
PI Notifies UNC	---	8	
Execute IRB Reliance Agreement	---	23	---
Total Processing Time to Final Approval	55*	58	35

*Some studies required more than one review cycle to resolve all contingencies, lengthening the time to final approval

Coding of Local IRB Review (mean no. contingencies per study)



Use of “Escape Hatch” for Deferrals

- Two studies in the experimental arm (randomized to central IRB) were deferred by UNC IRB at initial review → referred to “escape hatch” mechanism



- One study removed from external review
 - Substantive issues subsequently learned due to investigator error/oversight
- One remained under external review after confirmation of issues

Researcher Satisfaction and Feedback


- 85% of respondents felt that reliance on central IRB would (ultimately) speed process
 - Problems encountered likely to resolve with increased utilization and experience
 - Institution-specific consent language (injury, COI)
 - Navigating multiple registration processes
 - Miscommunications with sponsor, CRO
- Staff perception of central IRB registration process
 - 2.5 “level of difficulty” on scale of 1-4

Conclusions

- 1/3 of initial reviews by convened Biomedical IRB are potentially eligible for outsourcing
 - Which means 2/3 are not!
- Our desire to explore an alternative to the traditional “sole provider” arrangement was well-founded
- There are potential time-savings of ~20 days per trial, provided standing agreements are already in place
 - Efficiency likely to improve with increased experience
- Contingencies identified by local review (on studies already review/approved externally) tend to be minor administrative issues
 - 2 of 43 studies in pilot were deferred by local IRB, but issues were readily resolved

Points to Consider

- The IRB frequently serves as a gatekeeper or checkpoint for other institutional reviews/concerns
 - HIPAA
 - Office of Clinical Trials (concordance of contract vs. consent)
 - Radiation Safety Committee
 - Investigational Drug Service
 - Institutional Biosafety Committee
 - Conflict of Interest
 - ESCRO (stem cell research)
 - Social Security Number (collection of PII, IRS reporting, etc)
 - Use of clinical labs (testing and billing)
 - Data Security
- If the local IRB is no longer serving this role... who does?



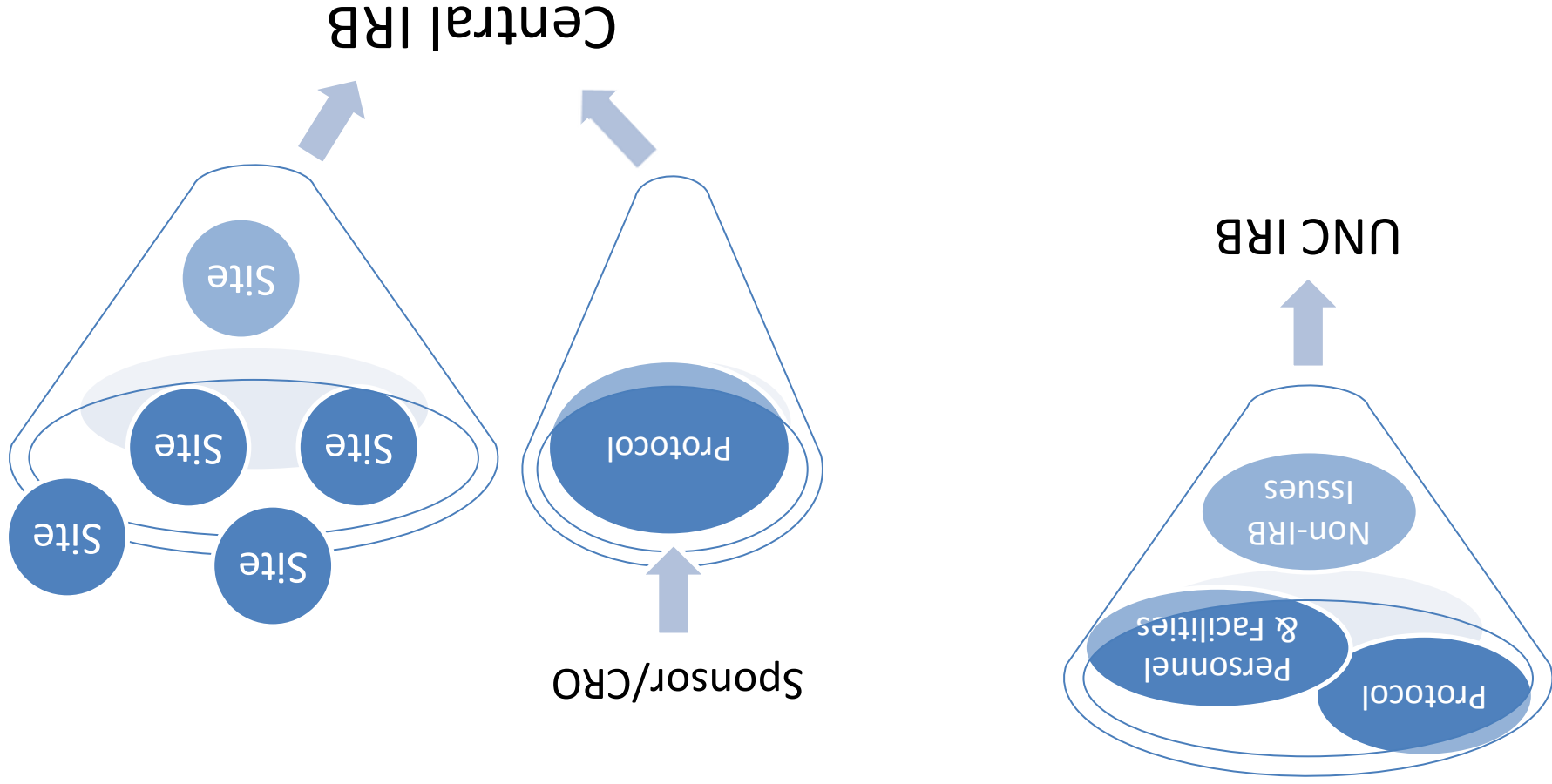
POSTSCRIPT:

Moving ahead with permanent policy and process

New Policy

- Effective October 15, 2013, UNC will rely on the approval and oversight of the independent/central IRB already involved with an industry-sponsored, multicenter trial, provided certain criteria are met
 - Sponsor/CRO has contracted with independent IRB to provide central review for any/all sites in that study
 - IRB is on UNC's pre-approved list
- What this is NOT...
 - Mandatory
 - Excuse to outsource homegrown, single site studies

Investigator interactions with central IRB shift from protocol review to site registration



Workflow

**Submit IRB
application
requesting
reliance on
Independent
IRB**

**Receive IRB
“stipulation”
letter with
permission to
use
Independent
IRB & CF injury
language**

**Register site
with
Independent
IRB**

**Satisfy all
Independent
IRB & UNC
requirements**

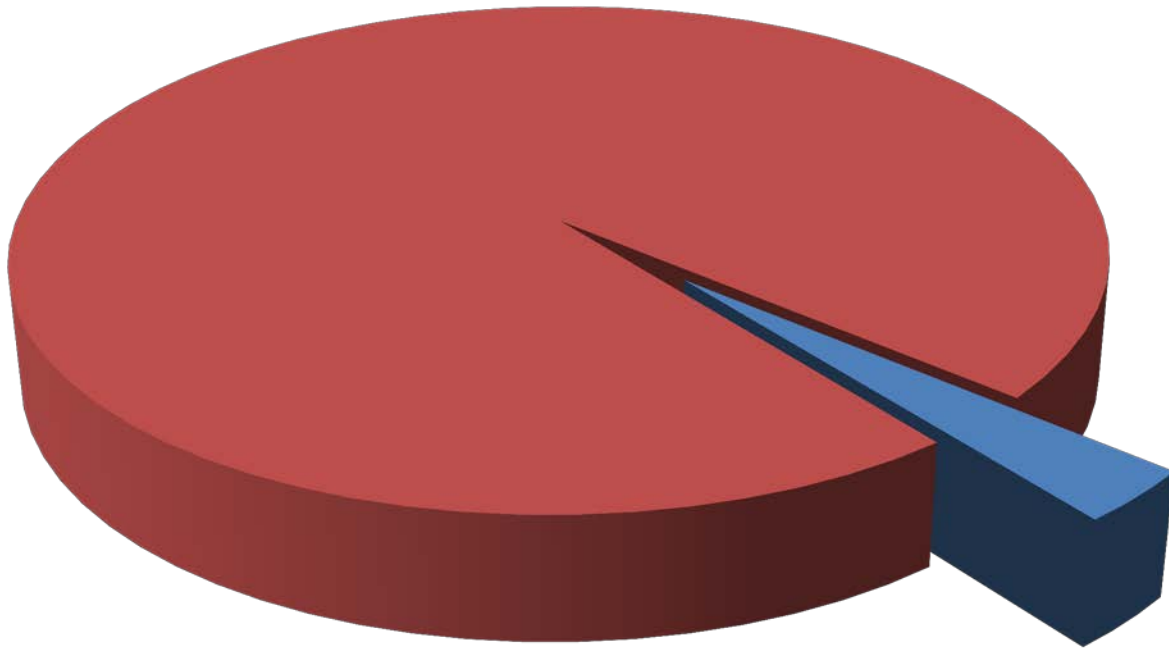
**Respond to
UNC IRB
stipulation
letter**

**Receive UNC
reliance letter
documenting
permission to
begin study**



**THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL**

The vast majority of IRBIS application questions have been suppressed



Approx 10-20 questions remain, depending on circumstances of individual study

CONTRIBUTORS

- **Pilot Project Team (co-authors)**
 - Diane Towle
 - Jonathan Hunter
- **Coding IRB Contingencies**
 - Barbara Waag-Carlson
 - Mary Lynn
- **CTSA Support**
 - Laura Cowan
 - TraCS leadership
- **Master Service Agreements**
 - Rebecca Schaefer, OUC
- **Consent Form Language**
 - Joy Bryde and Camilla Posthill, COI
 - Aylin Regulski, OCT
- **Other Pilot Supporters**
 - UNC Investigators and Study Staff
 - UNC IRB Members
 - UNC IRB Staff
 - Central IRB Staff



Research Institution Perspectives on Use of Central IRBs in the United States

**Cynthia Hahn, VP, Clinical
Research and Regulatory Affairs,
North Shore-LIJ Health System**

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Objectives

- ▶ **Differentiate the role of the institution and that of an IRB in a Human Research Protection Program (HRPP)**
- ▶ **Discuss the continuing and important role of the Institution in a Human Research Protection Program (HRPP) when utilizing a central IRB**
- ▶ **Share a case example of one institution's perspective**

Background

- ▶ **To improve the efficiency of conducting multicenter clinical trials in the United States, the Food and Drug Administration (FDA), the Office of Human Research Protections (OHRP), and the Department of Health and Human Services (DHHS) support the use of central IRBs.^{1,2}**
- ▶ **Research institutions' willingness to defer to centralized IRB review varies**

1. Guidance for Industry - Using a Centralized IRB Review Process in Multicenter Clinical Trials; March 2006
2. Menikoff J. The paradoxical problem with multiple-IRB review. N Engl J Med. 2010; 363:1591-1593.

CTTI Project:

► Goal

Identify solutions to address barriers to the adoption of central IRBs for multicenter clinical trials

► Objectives

- Solicit current perceptions of barriers
- Develop a strategy to address the identified barriers
- Assess reactions to proposed solutions to remove these barriers

Using Central IRBs for Multicenter Clinical Trials in the United States


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Abstract

Research institutions differ in their willingness to defer to a single, central institutional review board (IRB) for multicenter clinical trials, despite statements from the FDA, OHRP, and NIH in support of using central IRBs to improve the efficiency of conducting trials. The Clinical Trials Transformation Initiative (CTTI) supported this project to solicit current perceptions of barriers to the use of central IRBs and to formulate potential solutions. We held discussions with IRB experts, interviewed representatives of research institutions, and held an expert meeting with diverse stakeholder groups and thought leaders. We found that many perceived barriers relate to conflating responsibilities of the institution with the ethical review responsibilities of the IRB. We identified the need for concrete tools to help research institutions separate institutional responsibilities from ethical responsibilities required of the IRB. One such tool is a document we created that delineates these responsibilities and how they might be assigned to each entity, or, in some cases, both entities. This tool and project recommendations will be broadly disseminated to facilitate the use of central IRBs in multicenter trials. The ultimate goal is to increase the nation's capacity to efficiently conduct the large number of high-quality trials.

Flynn KE, Hahn CL, Kramer JM, Check DK, Dombeck CB, et al. (2013) Using Central IRBs for Multicenter Clinical Trials in the United States. PLoS ONE 8(1): e54999. doi:10.1371/journal.pone.0054999

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Common Themes

- ▶ **Concerns seemed to be associated with conflation of the responsibilities of the institution with the ethical review responsibilities of the IRB**
- ▶ **Remaining discomfort due to lack of experience using centralized review**

Recommendation #2

- ▶ **To address blurred distinctions between responsibilities for ethics review and other institutional obligations, CTTI recommends that sites and IRBs use a CTTI-developed guide to support communication and contractual relationships between institutions and a central IRB.**

“Considerations” Document

- ▶ **Considerations in Assigning Responsibilities to a Central IRB and a Local Institution for a Multicenter Clinical Trial**
 - ▶ Tool created by the project team, which clearly delineates responsibilities and how they might be assigned to each entity (IRB or Institution), or, in some cases, both entities.
 - ▶ The purpose is to outline categories of legal and ethical responsibilities of an institution and an institutional review board (IRB) in overseeing the conduct of clinical trials.
 - ▶ The document is meant to support communication between institutions and external, central IRBs

Considerations Document: Roles Defined

- ▶ **Central IRB**
- ▶ **Institution**
- ▶ **Either Central IRB or Institution**
- ▶ **Both Central IRB and Institution**

Example Roles Defined: Central IRB

- ▶ Register with FDA and OHRP
- ▶ Review clinical trials for compliance with regulations
- ▶ Provide investigator with copies of all IRB approvals
- ▶ Collect, review, and take into account site specific information
- ▶ Review and approve informed consent
- ▶ Notify the institution promptly in writing of serious or continuing non compliance, harm to subjects, or any unanticipated problems involving risks to subjects or others.
- ▶ Notify the institution promptly in writing of a suspension or termination of IRB approval and any remedial actions required.

Example Roles Defined:

▶ **Not Protocol Specific**

- ▶ Maintain program for education and training for human subject research
- ▶ Maintain policies and procedures for the conduct of human subject research
- ▶ Maintain appropriate institution specific credentialing of staff
- ▶ Maintain appropriate approved FWA, ensure that Central IRB arrangements are documented by a written agreement
- ▶ If accredited, maintain all functions relevant to maintenance of accreditation.
- ▶ *Conduct a privacy and security review as required by HIPAA with respect to the use and disclosure of PHI*

Example Roles Defined: Institution

► **Protocol Specific**

- Ensure IRB approval is obtained for research protocols involving human subjects
- For PHS funded research conduct a conflict of interest review pursuant to PHS regulations on promoting objectivity in research
- Ensure that the investigators are conducting research in accordance with IRB approved protocols, procedures and documents

Roles Defined: CIRB and Institution

▶ **Execute an IRB Authorization Agreement**

- ▶ Develop a SOP detailing roles and timeframes for reporting to sponsors, and applicable agencies serious adverse events, serious and continuing non-compliance, or unanticipated problems involving risks to subjects or others
- ▶ Clearly communicate expectations including requirements, sharing of information, and potential disciplinary actions in the event of non-compliance
- ▶ Develop a communication plan for sharing information about the site, investigators, sponsor, and the clinical trial including communication about any substantive changes

Case Example

- ▶ **Whether your institution agrees to rely on an “external” IRB or agrees to serve as the “central” IRB.**
 - ▶ An IRB Authorization or Reliance Agreement must be executed
 - ▶ The IRB Authorization or Reliance Agreement should outline the responsibilities of each party
 - ▶ How you get from agreement to implementation...well that's another story

Steps to Successful Reliance

- ▶ **Employ Change Management Techniques**
 - ▶ Assess your institutional culture
 - ▶ Establish goals and deliverables (plan!)
 - ▶ Identify potential champions and naysayers
 - ▶ Involve Stakeholders early and often
 - ▶ Provide regular feedback
- ▶ **Develop metrics: “What does success look like?”**

Steps to Successful Reliance

- ▶ **Assess Institutional Culture: scope your reliance and ask questions**
- ▶ **Would you consider:**
 - ▶ All kinds of studies open for reliance?
 - ▶ Any IRB, commercial, federal, academic for reliance?
 - ▶ If commercial: a single commercial IRB that your institution has contracted with or the IRB that “comes” with the study?

Steps to Successful Reliance

▶ **Assess Institutional Culture: scope your reliance and ask questions**

- ▶ If your institution is hesitant consider pilot reliance in certain studies or with certain groups first
- ▶ Set milestones! As with all “pilot” projects there should be a deliverable (report out) at a set point where a decision should be made:
 - ▶ discontinue the program (why?)
 - ▶ continue the program for X when the next report is due
 - ▶ expand the program

Steps to Successful Reliance

- ▶ **Establish Goals and Deliverables**
 - ▶ What is your desired outcome and timeline?
 - ▶ Stakeholder assessment: Identify your champions and your naysayers and everyone in between!
 - ▶ Develop your project plan: who, what, and when
- ▶ **Identify metrics: “What does success look like?”**

Steps to Successful Reliance

► Stakeholder Engagement

- Start the conversation and continue it formally and informally
- Hold meetings but also develop an elevator speech for those hallway conversations.
 - “I just participated in a webinar around alternative to conduct ethical review for multicenter studies that involve people. One way would be to use a central IRB for multicenter studies, which would mean a single IRB review for all sites. Have you ever considered this? How do you think we could implement such a program here?”
- Hold focus groups from across diverse groups of stakeholders to develop workflow, revise forms and inform for necessary policy or procedure changes.
- Provide regular updates, communicate, communicate, communicate

Steps to Successful Reliance

- ▶ **Plan and Develop a Business Model**
- ▶ **Execute the Model: Just Do it!**
- ▶ **Assess, Reassess and Report Out**

Case: North Shore-LIJ Health System

- ▶ **NSLIJHS is a 16 hospital, 2500+ employed physicians, health system based in the NYC and suburban NY area, geographic reach covers the majority of NYC and Long Island. Currently the 3rd largest secular health system in the US.**
- ▶ **The HRPP manages over 2,000 HRPP projects and our investigators are very collaborative.**

Case: North Shore-LIJ Health System



A vintage black and white photograph of actress Dinah Sheridan. She is smiling and looking towards the camera, holding a large, polished silver pressure cooker with both hands. She is wearing a green jacket over a white collared shirt. The background is a plain, light-colored wall.

DINAH SHERIDAN, our "cover girl" this issue, is really pleased with her Hawkins and kindly posed for this picture specially for Silver Lining—stars in their sphere!

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Case: North Shore-LIJ Health System

- ▶ **How do we build efficiencies into the process while still maintaining ethical and compliant systems for our HRPP?**
 - ▶ Since 2003 NSLIHS has been partners with with 4 other academic centers in New York in establishing an IRB to review industry sponsored clinical trials.
 - ▶ However, until recently the institution was reluctant to rely on a central IRB as defined here: as a single IRB of record.

Case: North Shore-LIJ Health System

Accepting Reliance on an External IRB

- ▶ **Initial Scope (phased approach):** NSLIJ started with minimal risk multicenter projects or studies where we were engaged from a regulatory perspective but minimally involved in the majority of study tasks.
- ▶ **Resource Allocation/Deliverables:** Allows the HRPP to focus on consultation for riskier studies, those involving vulnerable populations, to implement informed consent monitoring, GCP monitoring, investigations etc.

Case: North Shore-LIJ Health System

Accepting Reliance on an External IRB

- ▶ **NSLIJHS now routinely relies on external IRBs: commercial, academic, and federal and those reliance agreements may be based on a program, an institutional alliance or study specific.**
- ▶ **The HRPP workload has not lessened (in some areas it increased) but it has CHANGED**
- ▶ **Resources have been deployed in new ways, focus is more on oversight of study conduct and implementation at our institution, regardless of IRB utilized.**

Case: North Shore-LIJ Health System

Practical Tasks

- ▶ Educate the Institution about Institutional Responsibilities versus IRB Responsibilities!
 - ▶ Widely disseminate the Considerations Document
- ▶ Review and revise all policies and procedures:
 - ▶ “the investigator may not proceed without approval from the NSLIJHS IRB” to “the investigator may not proceed without approval from a NSLIJHS authorized IRB Committee”
 - ▶ “Contact the IRB Office” to “Contact the Human Research Protection Program”
 - ▶ IRB approval versus Institutional approval: who has the *final* say?

Case: North Shore-LIJ Health System

Practical Tasks

- ▶ Separate HRPP Policies from “IRB” Policies: Ensure you have institutional policies that apply regardless of IRB Utilized
 - ▶ Research with Human Subjects (IRB Approval)
 - ▶ Principal Investigator Responsibility for Human Subject Research
 - ▶ Informed Consent and Recruitment for Human Subject Research
 - ▶ Training in the Conduct of Human Subject Research
 - ▶ Compensation for Research Subjects
 - ▶ Review and Management of Conflict of Interest in Research
 - ▶ Maintenance, Storage, and Archiving of Human Subject Research Data
 - ▶ Access Use and Disclosure of Protected Health Information for Research
 - ▶ Human Subject Research Oversight, Monitoring, and Reporting

Case: North Shore-LIJ Health System

Practical Tasks

- ▶ Review and revise process and forms to facilitate institutional review:
 - ▶ Separate ethical tasks from administrative tasks
 - ▶ Decide what body within the organization will be authorized to provide “institutional approval” once IRB approval is in place
 - ▶ Do not duplicate questions or add in new layers of approval without first assessing why those questions appeared on the IRB forms in the first place.
 - ▶ Consider whether your institution would want to be relied on. What information would you need if you were the IRB of record?

Case: North Shore-LIJ Health System

- ▶ **Application for use by collaborative sites which wish to rely on NSLIJHS IRB:**

<http://www.feinsteininstitute.org/wp-content/uploads/2013/02/External-Site-Questionnaire-09-10-12.doc>

- ▶ **Application for use by NSLIJHS investigators who wish to rely on an external IRB:**

http://www.feinsteininstitute.org/wp-content/uploads/2013/02/Application-for-External-IRB-Use_8.29.13.doc

Case: North Shore-LIJ Health System

- ▶ **Application for use by NSLIJHS investigators who wish to rely on an external IRB:**
 - ▶ Sections on HIPAA (Privacy and Security), Required Training and COI Disclosure
 - ▶ Institutional Approvals (check and obtain all that apply, note it is the local investigator's responsibility to know and follow all local policies regarding clinical research):
 - ▶ Investigational Drugs Approval: _____
 - ▶ Radioactive Material Approval: _____
 - ▶ Recombinant DNA Approval: _____

Case: North Shore-LIJ Health System

STATEMENT OF COMPLIANCE

If the External Institutional Review Board approves this project, I agree to:

- Execute the research plan as described in protocol, including obtaining informed consent from all subjects as deemed appropriate by the IRB.
- Accept responsibility to comply with the standards and requirements stipulated in the above documents and to protect the rights and welfare of human subjects involved in research conducted under this protocol
- Comply with all other applicable federal, international, state, and local laws, regulations, and policies that may provide additional protection for human subjects participating in research conducted under this application.
- Report immediately to this Institution any unanticipated problems involving risks to subjects or others in research covered under this protocol
- When responsible for enrolling subjects, obtain, document, and maintain records of informed consent for each such subject or each subject's legally authorized representative as required under HHS regulations at 45 CFR part 46 and stipulated by the IRB.
- Report to sponsors and agencies as required.
- Maintain records of research, including consent documents, for a minimum of six (6) years beyond the termination of the study or, if longer, as specified by the funding agency/sponsor of the project.

There will be routine audits of research protocols by Research Compliance. Failure to comply with any of the above regulations may result in CLOSURE OF THE STUDY by this institution.

PRINCIPAL INVESTIGATOR STATEMENT

I hereby assure compliance to the above and assume responsibility for all activities involved in this project.

Printed name of PI

Signature of PI

Date

Case: North Shore-LIJ Health System

▶ **Establish the Business Model:**

- ▶ Define Workflow for the investigator, institution, institutional HRPP, and central IRB: who, what, and when
- ▶ Evaluate Costs
- ▶ Establish and publish a HRPP fee structure
 - ▶ Communicate with and educate your grants office and/or your clinical trials office

▶ **NSLIJHS builds into budgets study start up and administrative fees.**

Human Research Protection Program

- ▶ **Distinctions of a Quality Program as per AAHRP**
 - ▶ Strong integrated plan for human research protection
 - ▶ Strong program for scientific review
 - ▶ Strong and highly motivated organizational leader
 - ▶ Program for review of resources for the HRPP
 - ▶ Research specific IRBs
 - ▶ Strong network of communication among units
 - ▶ Policy and procedure to identify and manage organizational conflict of interest
 - ▶ Strong quality improvement programs
 - ▶ Strong education programs for researchers and staff
 - ▶ Highly competent IRB chairs, members, or staff
 - ▶ Impressive educational materials for the community

▶ THANK YOU



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For questions about the Use of Central IRBs
projects contact: **sara.calvert@duke.edu**

www.ctti-clinicaltrials.org