



Literature Review

Devon Check

Duke Clinical Research Institute

Search Terms

“Regional IRB”

“Multicenter IRB”

“Multi-site IRB”

“Central IRB”

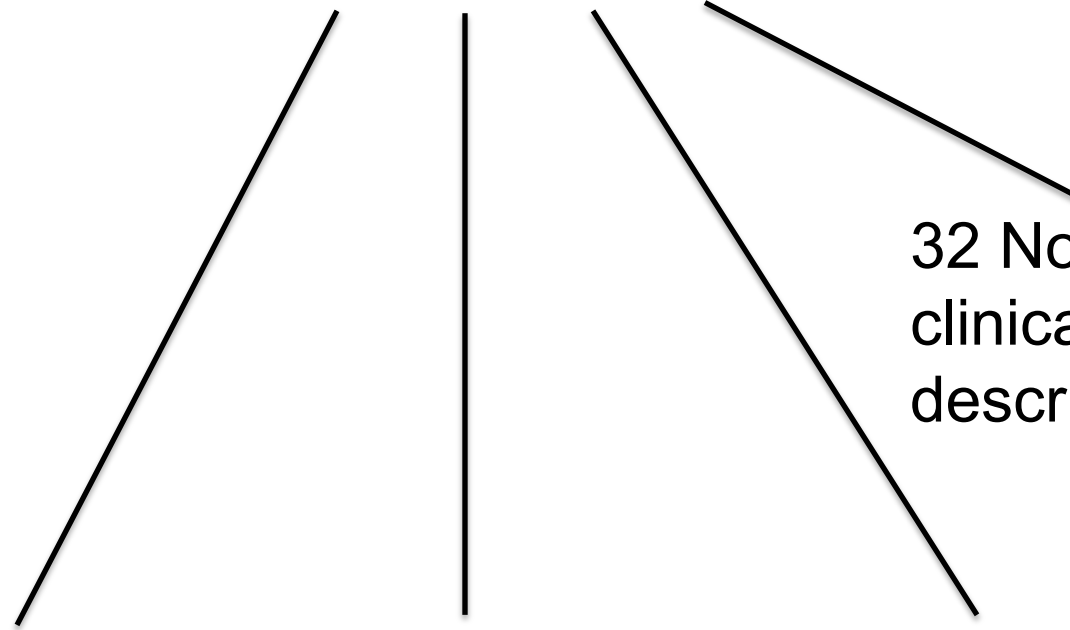
“Multiple IRB”

“Regional ethics committee”

“Central ethics committee”

“Clinical trial” and “monitoring” combined
with “IRB”

67 articles



32 Non-U.S.; non-clinical research; descriptive articles

Problems with Multiple Local Review

Multiple Local vs. Central Review

Barriers to Adoption of External IRB Review

Commentary	16
Empirical	10

2
1

4
2

35 articles

Problems with
Multiple Local
Review

Multiple Local
vs. Central
Review

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Problems with Multiple Local Review

Local IRBs overburdened

Duplication of effort

Inefficient use of time and resources

Delays research

Variability in evaluation by different IRBs



The NEW ENGLAND
JOURNAL of MEDICINE

The Paradoxical Problem with Multiple-IRB Review

Jerry Menikoff, M.D., J.D.

The federal system for protecting research subjects was designed decades ago, when most research studies took place at a single institution. These days, if a study is conducted at multiple sites, an ethics review by an institutional review board (IRB) may be repeated many times. This practice has been criticized for

resource-intensive effort at least substantially improves the ethical integrity of multisite studies. In fact, however, there is reason to believe that not only do these duplicative reviews provide relatively few benefits, but the current framework may actually reduce the likelihood that studies are in keeping with relevant eth-

by an IRB, which must make various determinations regarding the risks and benefits of the study and the adequacy of the informed consent to be obtained from subjects. Each institution engaged in the research — and thus generally each individual study site — must obtain IRB approval.

Since the precursors to the cur-

Redundant reviews at the local level do not appreciably enhance protection of human subjects, and may even weaken ethical integrity of protocol due to diffusion of responsibility.

Local Institutional Review Board (IRB) Review of a Multicenter Trial: Local Costs without Local Context

Bernard Ravina, MD, MSCE,¹ Lisa Deuel, BA,¹
Andrew Siderowf, MD, MSCE,²
and E. Ray Dorsey, MD, MBA¹

Methods

The trial was a randomized, double blind, phase III trial of coenzyme Q₁₀ and vitamin E, conducted by the Parkinson Study Group, at 52 U.S. sites. We compared the IRB-approved template consent and protocol, developed by the coordinating center at the University of Rochester, to each sites' IRB-approved version. We identified consent modifications that changed meaning and were relevant to local context. We measured the Fleisch-Kincaid reading level of the consent and reviewed each site's approved protocol for changes. Three raters coded the changes (L.D., B.R., A.S.), including one active IRB member (A.S.); disagreements were resolved by consensus. We examined

Examined the costs and effects of local IRB review of the consent documents and protocol in a multicenter clinical trial in Parkinson's disease

42 site clinical trial; 37 sites used their local IRBs

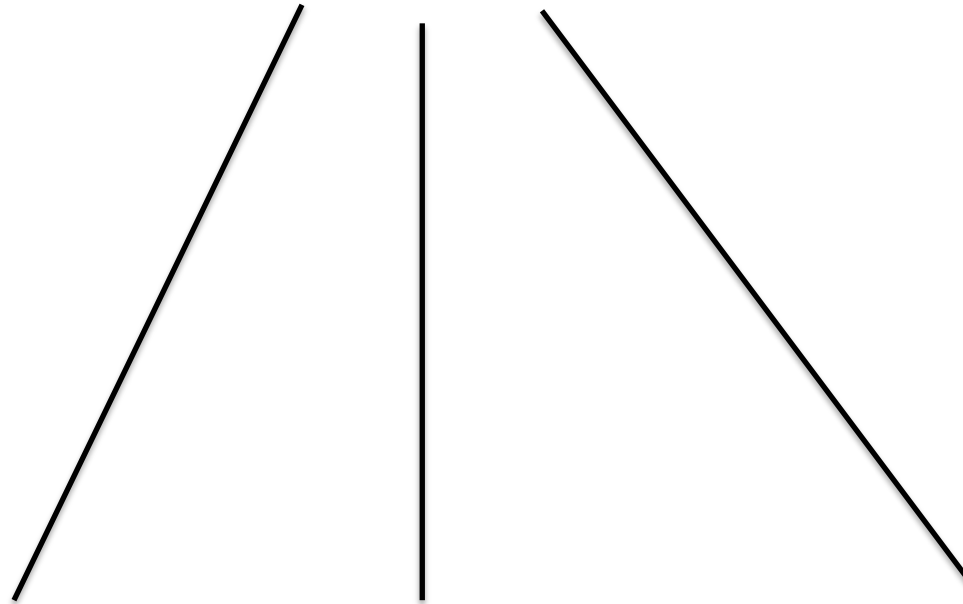
5.2 local changes to consent form per site
76% involved standard institutional language; 24% trial-specific information; 85% recruitment expectations

Consent forms longer, higher reading level

No substantive changes to protocol

\$107,544 in direct costs (IRB fees & labor)

35 articles



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JOURNAL OF CLINICAL ONCOLOGY

ORIGINAL REPORT

Costs and Benefits of the National Cancer Institute Central Institutional Review Board

Todd H. Wagner, Christine Murray, Jacquelyn Goldberg, Jeanne M. Adler, and Jeffrey Abrams

Surveyed oncology research and IRB staff to understand effort and timing

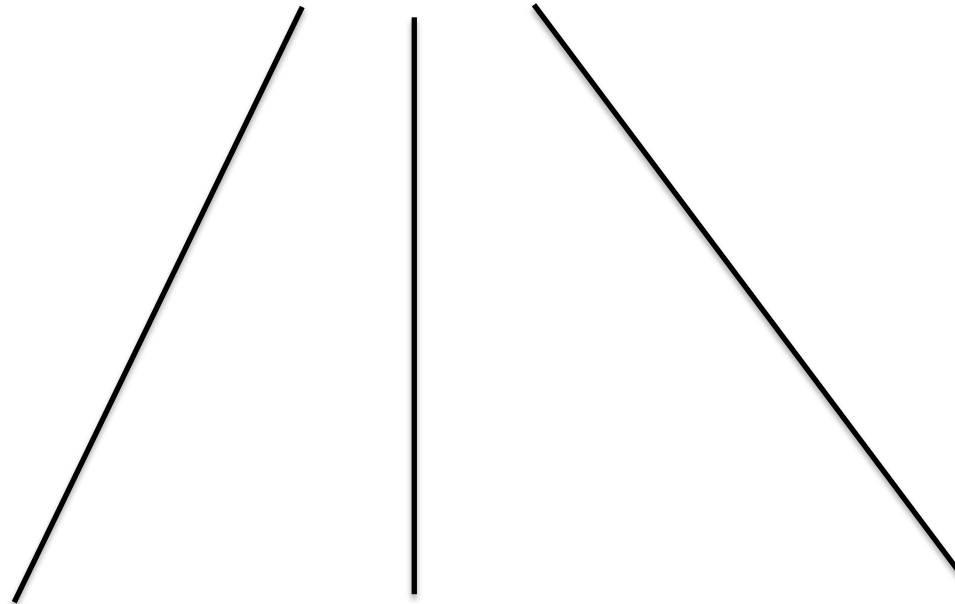
Combined with CIRB operational data to determine net savings from societal perspective

NCI CIRB affiliation associated with faster reviews (33.9 calendar days faster on average), and 6.1 fewer hours of research staff effort

Savings of \$717 per initial review

Savings of \$55,000/month from societal perspective

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SPECIAL THEME RESEARCH REPORT

Medical Schools' Attitudes and Perceptions Regarding the Use of Central Institutional Review Boards

Evangeline D. Loh, PhD, and Roger E. Meyer, MD

Deans of Research at 88 U.S. medical schools

24% had used a central IRB

76% had never used a central IRB

Concerns about institutional liability and loss of representation in review process

Local IRB works efficiently enough

Klitzman *BMC Medical Ethics* 2011, **12**:13
<http://www.biomedcentral.com/1472-6939/12/13>



RESEARCH ARTICLE

Open Access

How local IRBs view central IRBs in the US

Robert Klitzman

34 IRB leaders and 12 members and administrators

Local IRBs provide local knowledge and have responsibility to community

Concerns about quality of review by central IRB

For-profit central IRBs may have conflicts of interest

Conclusions

More commentary than empirical

Focus on efficiency versus quality

Conflicting use of language for describing different models of centralized review