Use of Central IRBs for Multicenter Clinical Trials

BARRIERS & SOLUTIONS

CLINICAL TRIALS TRANSFORMATION INITIATIVE

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Approach

Update barrier list

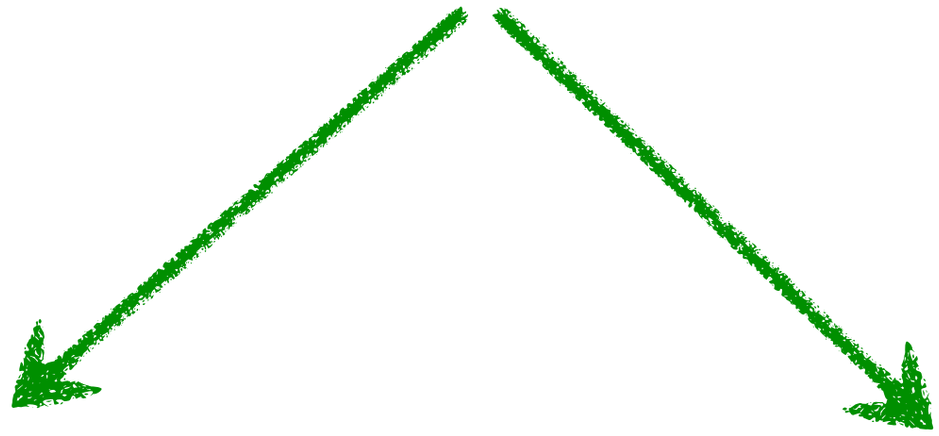
Propose solutions to remove barriers

Solicit reactions to proposed solutions from diverse stakeholders

Develop recommendations

Concerns About External IRB Review (2005-2006)

Update Barriers



Literature review

Expert Advisory Panel

Barriers to Central Review

Review quality (Local concerns)

Regulatory liability

Legal liability

Negative public relations

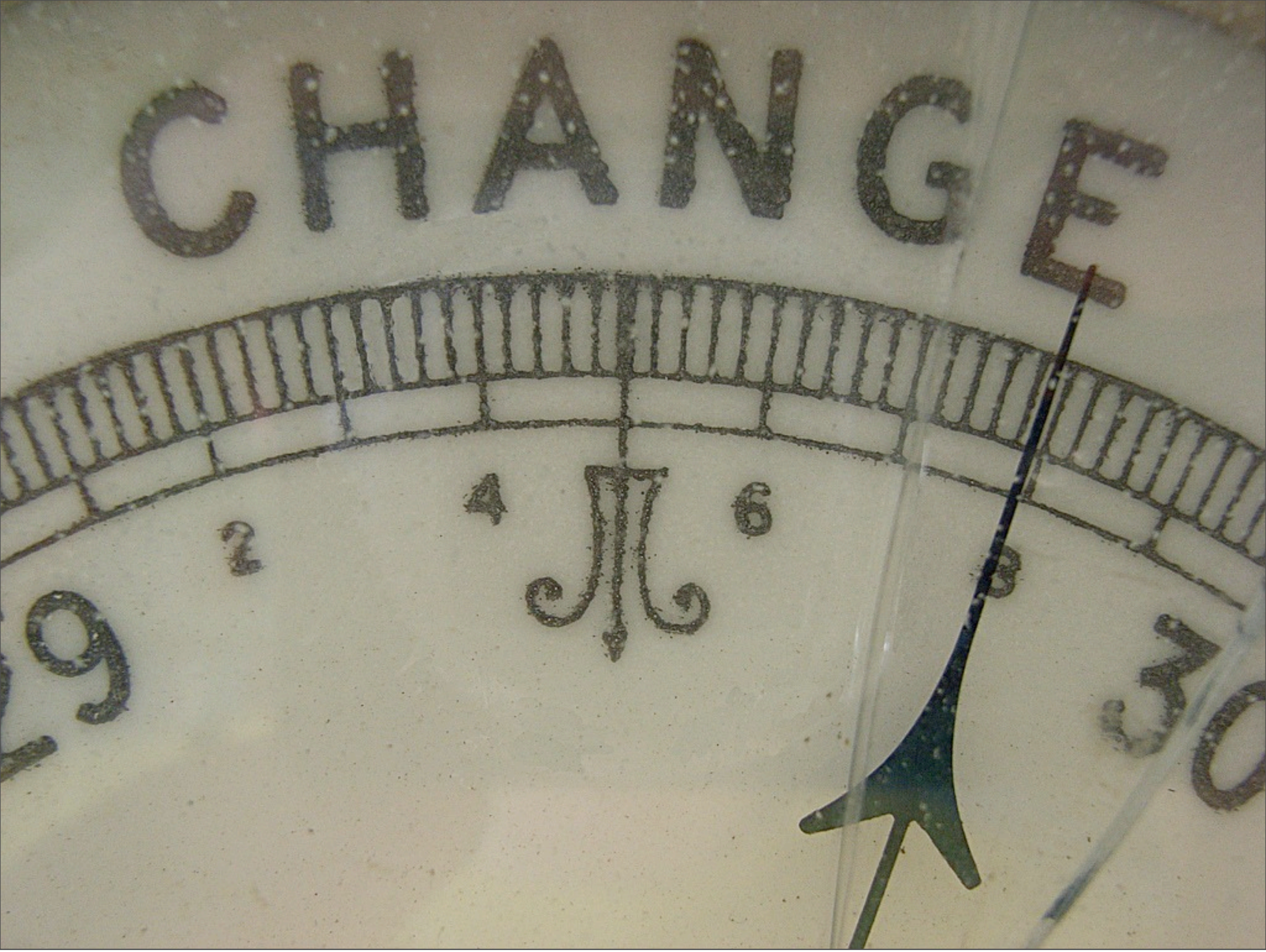
Loss of income from fees

Too many different forms


no solutions yet....

Inconsistent use of term

"Central IRB"



Wednesday, May 23, 2012

Current Practices

Independent IRBs

Federal IRBs

Consultants

An independent IRB is not the same as a central IRB

Federated Model

Sites in a network agree on reciprocal acceptance of one another's IRB review and approval

Consortium Model

Sites agree to a robust centralized review process but do not cede review responsibility to an external body

Facilitated Model

The protocol is reviewed by the central IRB, then handed down to the institutional IRBs to conduct what is essentially an expedited review

Single IRB of Record

Sites cede all regulatory responsibility for scientific oversight and integrity of the protocol from initial review to termination of the research, including review of informed consent, to the central IRB

Sponsors do not mandate use of a single IRB


still no solutions...

2011 ANPRM

Designate only one IRB of record

Regulatory liability falls on the IRB

Institutions would review for compliance with other regulatory requirements

Public Comments

RAND

Public Comments

PRIM&R

Public Comments

AAMC

Public Comments

IRB Forum

Generating Solutions

Accumulated knowledge

Additions to project team

Interviews with expert advisors

Proposed Solutions

Local Context

How much of a problem is this for the protocol?

Institution can add to informed consent

Institution can limit investigator involvement

Administrative

- Standardize forms

Financial

Institutional administration fee

Cover fixed IRB costs in another way

Legal & Regulatory

Clarification of OHRP policy to take action against IRB-of-record and not institution for noncompliance with regulations

Define roles of institution and IRB-of-record

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