

Managing local precedents

Three models

Challenges of multisite, multidisciplinary studies

National Academies of Science

22 March 2013

Professor Laura Stark

Center for Medicine, Health & Society

Vanderbilt University

laura-stark.com

laura.stark@vanderbilt.edu



IRBs Observed

	Sander State IRB	Greenly IRB	Adams Medical
Duration of observations	12 months	12 months	5 months
Meeting(s) per month	1	1	2
New full-board protocols in period*	40	20	60
Number of IRB members			
Community members	2	2	2
Faculty and administrators	12	11	9

Managing local precedents

Issue

Local precedents

Approaches

Three models

Questions

Merits of models; priorities in revising regulations

The issue

ANPRM

“In many cases, a local IRB for each institution does independently review the research protocol, informed consent documents and other materials, sometimes resulting in hundreds of reviews for one study... This process can take many months and can significantly delay the initiation of research projects. Separately, there are reports showing that there can be widely differing outcomes regarding the level of review required from IRB to IRB, even for identical studies.”

HHS, 2011

The issue

Local precedents

Definition

- Past decisions that guide board members' evaluations of subsequent research (Stark 2012)

Consequences

- Faster decisions, internal consistency
- Board-specific idiosyncracies

Managing local precedents

Issue

Local precedents

Approaches

Three models

Approaches

Three models

- Study networks

Approaches

Three models

- Study networks
- Collegial review

Approaches

Three models

- Study networks
- Collegial review
- Decision repositories

Managing local precedents

Issue

Local precedents

Approaches

Three models

- Study networks
- Collegial review
- Decision repositories

Questions

What are the relative merits of the three models?

What are highest priorities in revising in 45CFR46?

Managing local precedents

Three models

Challenges of multisite, multidisciplinary studies

National Academies of Science

22 March 2013

Professor Laura Stark

Center for Medicine, Health & Society

Vanderbilt University

laura-stark.com

laura.stark@vanderbilt.edu