Site Interviews

Kevin Weinfurt, PhD
on behalf of CTTI Team
Considerations Document

Delineates ethical/regulatory responsibilities of IRB and local institution
Methods
The Sites
AMC = Academic Medical Center

AMC

AMC

AMC

Non-AMC

Non-AMC

Non-AMC
# participants

3

5

4

3

6

3
IRB Chair
IRB administrator/coordinator
Director of Human Research Protections
General Counsel
Corporate Responsibility
Research Integrity/Compliance officers
Institutional Official for Research (VP)
Interviews

General query first

Follow-up of specific barriers/issues

Review of Considerations Document
Findings
Meta-Themes

Enthusiastic support for project and Considerations Document

Comfort and Trust
Categories of Barriers

Legal & regulatory
Local context
Administrative & logistic
Financial
Conflicts of interest
Legal & Regulatory Barriers

Who will be held responsible in event of noncompliance?

Adherence to state regulations

Bear the risk without control
And one [concern] is the most common that I think I've heard from other institutions, as well, is our legal responsibility to the patients through our consent forms and through our contracts. And if we have not a lot of say in those contracts or in that information, we feel like we're taking the legal responsibility but without the ability to actually negotiate that on our own behalf.

IRB Chair
The oversight and main control, the ability to be the IRB of record and to make sure that they know exactly when to stop the studies, when something is happening within the studies ... It’s a control issue.

Senior Vice President of Research
Legal/Regulatory Solutions

Clarify responsibilities: Considerations Document

Clarification of OHRP policy to take action against IRB-of-record for noncompliance

Accreditation of central IRB

Plan for timely communication
By utilizing the central IRB, our IRB may be saying, "Hmm. Okay. Well, how long's it take for them to notify us of all of this? . . . Is this going to come in writing? How long is it going to take for us to get it? Is it going to be..." You know, just little small things.

Senior Vice President of Research
Local Context Barriers

- Investigators / staff
- Patient population
- Appropriateness and consistency of compensation
There was an NIH sponsored study where they were going to try and prophylactically treat signs of fever. And this was with regard to the fly from the South which produces that fever. But the frequency of the side effect of the prophylactic medication was higher than the rate of that flu virus here in [state]. So [we] declined to participate in study.

IRB Chair
Local Context

Solutions

Systematic plan for incorporating local concerns into central IRB review

(need models)

Consent form with customizable section for state/local concerns

Local institution has authority to participate or not
Administrative/Logistic Barriers

Need to review/maintain records for auditing

Different paperwork & software for each external IRB

How to coordinate what should be done centrally vs locally?
Administrative/Logistic Solutions

Delineating site vs IRB responsibility: Considerations Document

Standardized forms and software

Need models here!
Financial Barriers

Lose overhead from industry-sponsored trials

Preserving IRB jobs
Financial Solutions

Institutional administration fee to replace IRB review fee
Conflicts of Interest

Barriers

Concern about relationship between industry sponsor and independent IRB

Unease with sending sensitive COI info outside of institution

Institution may not want to communicate certain knowledge about investigators to an outside body
COI Solutions

Need reassurance about integrity of independent IRB

Need models for sharing COI information
Awesome

Understand how issues live within institution

Great examples

Move from barriers to needs, needs to solutions

Utility of Considerations Document