An Observational Descriptive Study of IRB Decision Making

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Background
Institutional Review Boards (IRBs) are the primary organizations designed to protect research subjects from harm and assure that they participate voluntarily. At the same time, many researchers feel that they intrude into the research process without making research safer.

Goals
- Identify which issues about applications are the focus of IRB attention; e.g., the scientific validity of a protocol, issues of risk, informed consent
- Clarify how, if at all, the occupants of different roles (chair, community member, attorney, scientific expert, etc.) differ in their discussion of applications
- Describe how IRB members identify problems in applications; what information resources they use and how they use them
- Identify how IRBs organize the work of application review through the use of staff, pre-meeting review and formal meetings

Data Analysis
Close coding of text, quantitative analysis of the frequency of issues discussed, and qualitative analysis of themes.

Study Questions
- What issues about applications are the focus of IRB attention; e.g., the scientific validity of a protocol, or issues of risk or informed consent?
- How, if at all, do the occupants of different roles (chair, community member, attorney, scientific expert, etc.) differ in their assessments and discussions of applications?
- How do IRB members identify problems in applications? What information resources do they use and how do they use them?
- How do IRBs organize the work of application review through the use of staff, pre-meeting review and formal meetings?

Sample
Two IRB panel meetings at each of 10 sites. Each site will be among the 25 largest medical research institutions in the U.S.

Early Findings of Interest
- There are a wide variety of ways of organizing the IRB review process
- Medically trained reviewers play a significantly larger and more substantial role in IRB reviews than community members
- The work of the IRB staff is highly organized and rule-bound; by contrast, the committee reviews are minimally structured and substantively focused
- Committees appear to spend most of their attention on minimizing risks to subjects and as-