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

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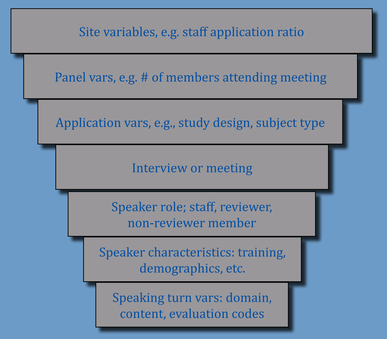
Data Collection

- Transcripts of audio recordings of a single meeting of each of 20 IRB panels.
- Interviews with:
  1. Panel Chairs
  2. Protocol reviewers
  3. IRB administrators
  4. IRB staff

Data Analysis

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



It is possible to conceptualize our preliminary quantitative model as a pyramid. The pyramid arranges variables from the most general organizational data (the way in which the IRB at a site is set up) to the most specific data, the textual data from the meeting and the interviews. In between are background data about the way the particular panel functioned on the day we observed, features of the studies being processed, whether the data come from an interview or the meeting and different types of background features of the speaker. The basic design of the quantitative analysis is to model the bottom of the pyramid in terms of the variables above.

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 assuring the quality of the research, and less time than expected on revising consent form language. However members in different roles focus on different issues.
- The overwhelming majority of the discussion takes place between the reviewers of a protocol and the chairs, with other members participating only under unusual circumstances.