



An Observational Descriptive Study of IRB Decision Making

Charles W. Lidz, PhD, Philip J. Candilis, MD, Paul Appelbaum, MD, Robert Arnold, MD, Albert J. Grudzinskas Jr, JD, William Gardner, PhD, Suzanne Garverich, BA, John Grillo, Lorna Simon, MA, Kim Smith, MA, Antonia Seligowski, BA & Tara Zandi, BS

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

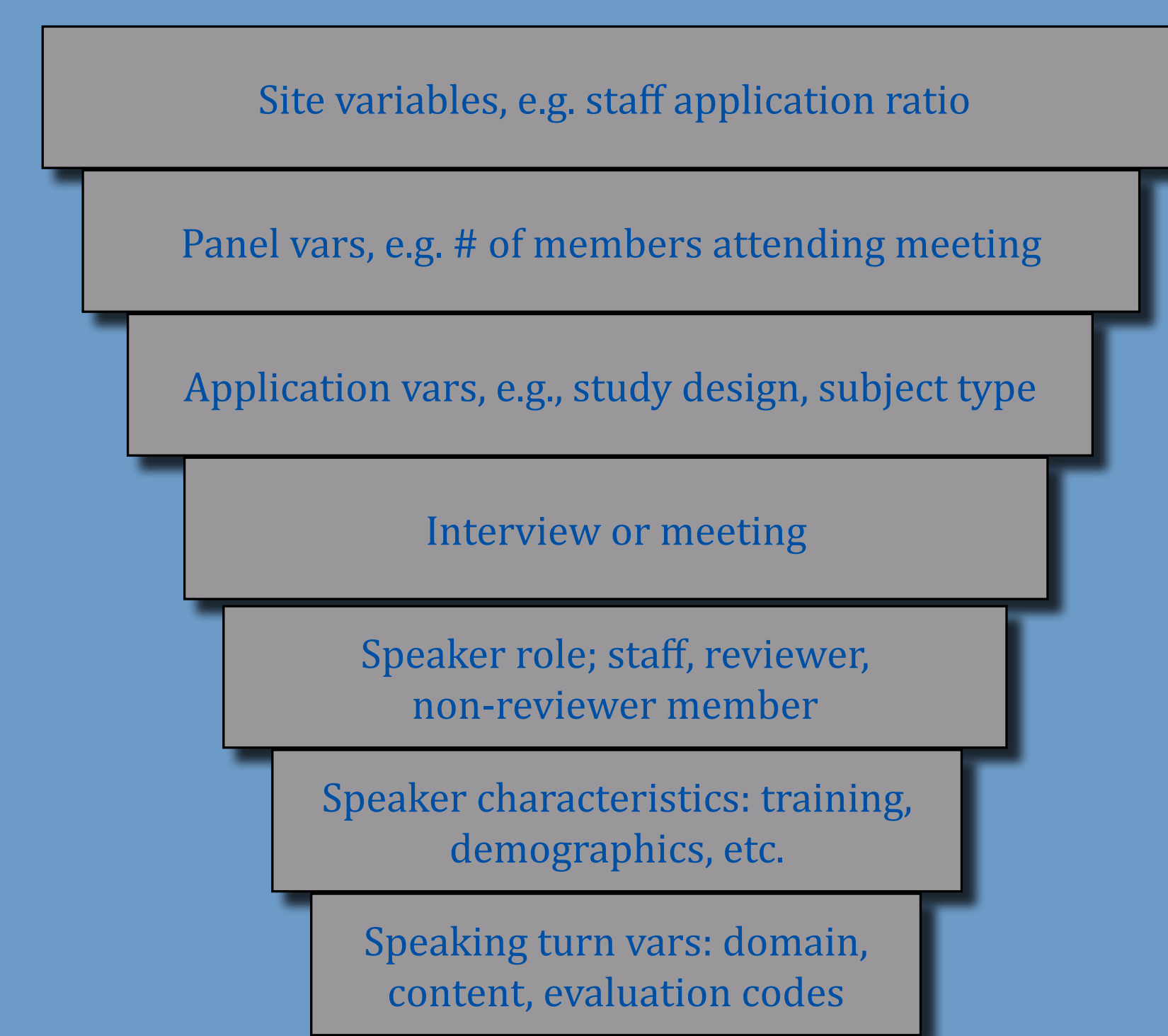
- Identify which issues about applications are the focus of IRB attention; e.g., the scientific validity of a protocol, issues of risk, informed consent
- Clarify how, if at all, the occupants of different roles (chair, community member, attorney, scientific expert, etc.) differ in their discussion of 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 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.

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?

Physician Committee Member: I just try and make sure that there's some scientific basis behind what they're proposing to do... and then I try and make sure the safety parameter that they're proposing they follow, are appropriate and adequate, and then I usually summarize my comments so it's that it's generally my opinion, and I then hope that someone, the secondary reviewer, or other people who have potentially more expertise in the given area if I don't, would have more opinions as well.

Reviewer: I read the consent form and I sort of have like a little um, game that I play. I imagine that its my mother who's being presented with this consent form, could she understand it? Um, you know would I feel like she knew what she was getting into, would I feel like she had a good sense of what her risks were, um, you know somebody who's not necessarily educated like us.

Attorney Committee Member: I'm neither a statistician nor a physician, or a nurse or anybody who would be able to make reasonable sense out of the medical side of things. So I figure my main goal there as a lay person is to look at what the hell they're doing and see whether the consent form... fairly decides what's going on and most particularly fairly decides whatever risks they're asking you to undergo.

Interviewer: When ...[if] the medicine that they're using is kind of advanced do you ever end up using outside sources or...look things up on the internet or ...books or call the PI? Do you do any of that?

Chairperson: Yeah, I do use the internet a fair amount to figure out what the drugs are and what they do. If I don't understand it...sometimes I've contacted [the Chair] occasionally with questions and I've contacted PIs occasionally...but you know [I] rely on the...oncologist here to... be able to answer them.

Reviewer: I think that the science needs to be looked at because, as I'm sure some people have said, if the science isn't valid then any subject who's in that study is needlessly put at risk because no knowledge will be gained from it...alone, with probably the other physicians, kind of do it, depending on where the protocol comes from. So if its an NIH protocol, we do pretty much say yeah, a lot of really good minds have already looked at this. It's been approved. It would not have gotten funding if it hasn't already meant really stringent criteria.

Lay Member: "I think generally the idea is to get the people that really should not be primary reviewers, to be the secondary reviewer. You want lay people, or the...you know, the pharmacists, or the lawyers, or nurses...to be the secondary reviewers."

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.

Contact Information

Charles W. Lidz, PhD, Psychiatry
Phone: 508-856-8716
E-mail: charles.lidz@umassmed.edu

Suzanne Garverich, BA, Psychiatry
Phone: 508-334-0548
E-mail: suzanne.garverich@umassmed.edu

Professional Background

