The Ideal IRB: What Do Scientists Want?

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Disclaimer Note

The good news and the bad news.

38% of our large national sample of researchers expressed satisfaction with their IRBs.

62% less so.

(10% are VERY dissatisfied with their IRBs).

Common Anecdotal Complaints about IRBs

"Dealing with our IRB is like jumping through hoops."
"It's a love-hate relationship."
"It's like going into a lion's den."
"My IRB is full of Neanderthals!"
"Our IRB chair is the devil incarnate."

The above are garden variety gripes—but the next examples are the ones that concerned us.

"Don't tell anyone, but my IRB is so picky that I don't put everything I am actually going to do in the protocols I submit to them."

"My IRB is so off-putting that I do anything I can to work around them."

"Our IRB is so incompetent that I don't put my protocols through it. They will never figure it out."

Common Complaints from the Literature About IRBs

- Excessive time delays
- Unprepared for meetings
- Incompetent
- Superficial and hasty review of protocols
- Using extraneous criteria rather than of scientific merit to evaluate protocols
- Arrogance (demeaning or rude attitude towards investigators)

(Literature-based complaints about IRBs, continued)

- Mostly interested in wielding power
- Uncommunicative (unresponsive to inquiries)
- Insufficient opportunity to appeal negative decisions
- Conflicts of interest
- Favor their friends or others who might reciprocate favors
- Censorship of legitimate research topics
- Lack of accountability

(Literature-based complaints about IRBs, continued)

- Lack of expertise in research methodology and techniques
- Overly conservative criteria applied to innovative research
- Use of the "local standard loophole" to justify idiocyncratic decisions
- Harassment of investigators who complain
- Paranoia (fear that the institution will becriticized supercedes scientific merit)

The Search for the *Ideal* IRB

The Sample

- N= 886 who returned usable surveys (38.8% of the 2283 randomly selected PHS PIs and APS researchers who received surveys)
- Respondents were asked to rate the importance in their own work of 45 IRB functions on a 7 point scale (7=extremely important to 1=not important)
- Respondents were also asked to rate how their own IRB compared to their ideal IRB, and to identify their research specialty type, past IRB service history, percentage of exempt research conducted, and gender.

The 12 Most Important IRB Characteristics (Letterman list style!)

#12. An IRB that includes a complete rationale when it denies or mandates changes in a protocol based on criteria that are more stringent than or different from federal research policy (i.e., application of "local standards") (5.59, 1.35)

#11. An IRB whose members fully understand and act within the scope of their function (5.67, 1.27)

#10. An IRB that works with investigators to find mutually satisfying solutions whenever disagreements exist (5.71, 1.27)

#9. An IRB that gives a complete rationale for any required changes to or disapprovals of protocols (5.73, 1.21)

#8. An IRB that responds in a timely manner to investigators' inquiries about its processes and decisions (5.80, 1.15)

Most Important IRB Characteristics (Continued)

#7. An IRB that views protection of human participants as its primary function (5.80, 2.83)

#6. An IRB that conducts a conscientious and complete review of protocols (5.86, 1.24)

#5. An IRB with members who are very knowledgeable about IRB procedures and federal policy (6.01, 1.16)

#4. An IRB that does not use its power to suppress research that is otherwise methodologically sound and in compliance with federal policy whenever it perceives potential criticism from outside the scientific community (6.08, 1.19)

Top Three IRB Characteristics

#3. An IRB that does a good job of upholding participants' rights while, at the same time, facilitating the conduct of research (6.10, 1.11)

#2. An IRB with members who do not allow personal biases to affect their evaluation of protocols (6.17, 1.10)

#1.An IRB that reviews protocols in a timely fashion (6.43, 0.80)

Least Important IRB Characteristics

#41. An IRB that offers consultation during the development of research protocols and grant applications (4.30, 1.76)

#42.An IRB that has a diverse membership (i.e., includes women, minorities and junior and senior members of the institution) (4.07, 1.93)

#43. An IRB that offers investigators opportunities to be educated about federal research policy (4.03, 1.68)

#44. An IRB that offers editorial suggestions regarding consent documents and protocols (typos, grammar, clarity, etc.) (3.20, 1.82)

#45. An IRB that is composed of more than one public member (2.68, 1.69)

Other Findings of Interest

The 8 Apriori Factors Were Confirmed (a single item didn't load)

1. Procedural justice (*how the decision-making process is carried out*)
2. Absence of bias (*a feature of procedural justice*)
3. Competence (*how well IRB functions are performed, a feature of procedural justice*)
4. Interactional justice (*interpersonal sensitivity*)
5. Pro-science sensitivity and commitment
6. Formalities (*committee's structural functioning*)
7. Upholding rights of research participants
8. IRB outreach (*offering consultation, etc.*)

Overarching Findings

- Justice issues more important to investigators than other kinds of issues, with procedural and interactional justice being higher than for pro-science sensitivity and absence of bias.
- Overall negative skewness (i.e., most items judged to be fairly important, with a small but statistically higher rating among Biomedical than Social/Behavioral investigators)

Other Findings

- Those who were dissatisfied with their own IRBs rated interactional justice items (that is, treating investigators with respect) as more important than those who were satisfied
- No gender differences
- No significant differences between those whose research requires full review and those whose research is primarily exempt
- No differences between those who have served on IRBs and those who had never served
- No differences between less experienced and experienced investigators

Small but statistically significant differences between Biomedical and Social/Behavioral Investigators

BM investigators gave higher ratings to formalities than did SB investigators.

BM investigators more concerned with allocation of sufficient resources

SB investigators more concerned with ability of IRB's competence to make the distinction between exempt and nonexempt research.

CONCLUSION: The apriori factors were confirmed (confirmatory factor analysis through structural equation modeling), and the planned MANCOVAs revealed that differences among our sample were either nonexistent or small.

Practically speaking, this means that characteristics of IRBs override differences among investigators. Thus, we were able to develop a tool that any institution can use for self-study of its own IRB and consult the PHS/APS sample for comparison purposes.

The IRB-RAT

IRB Researcher Assessment Tool

Posted for your free use (including comparison sample data) at

www.ethicsresearch.com

The authors would appreciate hearing about experiences using the IRB-RAT.