

## Variability in Institutional Review Board Assessment of Minimal-risk Research

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### Abstract

**Objectives:** To examine variability in responses from institutional review boards (IRBs) to submission of a proposed minimal-risk survey. **Methods:** Identical research proposals to obtain information concerning beliefs about the needs of victims of intimate partner violence via surveys were submitted for IRB approval to three institutions in the Baltimore metropolitan area. One institution is an academic center, one is an inner-city hospital affiliated with the academic center, and the third is a suburban community hospital. The study population consisted of emergency department health care providers and individuals in emergency department waiting areas. **Results:** Inconsistencies emerged among the three IRBs in the review process itself, the need for participant consent, and the need for revision of the consent form and study protocol. One institution approved the proposal in

15 business days after expedited review. The second institution approved the proposal in 12 business days and waived the requirement for informed consent. The third institution approved the research in 77 business days after three revisions. Questions raised included: methodology for selecting participants; appropriateness of surveying individuals in emergency department waiting areas; a request for background literature to assure that the research questions had not already been answered; and concerns about study methodology and sample size justification. **Conclusions:** In this sample, there is considerable variability in IRB processes even for minimal-risk studies. **Key words:** IRB; institutional review board; minimal-risk studies; variability; surveys. *ACADEMIC EMERGENCY MEDICINE* 2002; 9:1417-1420.

Institutional review boards (IRBs) are designed to ensure the ethical treatment and protection of individuals who participate in scientific research.<sup>1</sup> As stipulated in the Public Health Service Act, medical institutions that receive federal funding must have IRBs.<sup>2</sup> Although IRBs have become a significant part of the academic landscape, problems still occur with human subject research.<sup>3</sup>

Documentation of the variability and inconsistencies in the IRB approval process is important in order to develop potential solutions to this problem in the future. Institutional review boards have shown significant variability in their critique of proposed multicenter clinical trials.<sup>4,5</sup> However, to the

best of our knowledge, no reports have been published about inconsistencies in the review of observational studies, many of which pose minimal risk to subjects and are free of commercial conflict of interest. Per the Code of Federal Regulations, the formal IRB designation of "minimal risk" can be defined as the probability that the magnitude of harm or discomfort anticipated in the research is not greater in and of itself than what would ordinarily be encountered in daily life or during the performance of routine physical or psychological examinations or tests.<sup>2</sup> Furthermore, observational studies have contributed significantly to our current medical knowledge. This report examines the variability in IRB approval for a minimal-risk survey and illuminates inconsistencies in the institutional review process.

### METHODS

**Study Design.** This study is a nonstandardized descriptive review of the process required to obtain IRB approval for a minimal-risk survey. The survey was developed as part of a graduate level course on health survey research methodology and designed to study the beliefs and expectations of emergency department (ED) health care providers

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and individuals in ED waiting areas regarding the needs of victims of intimate partner violence (IPV).

**Study Setting and Population.** The IPV screening survey was to be administered at three separate medical institutions within the Baltimore metropolitan area. Institution X is an academic tertiary care hospital whose main adult ED has a total annual patient census of 37,000. The patients primarily come from nearby predominantly African American neighborhoods. Screening for IPV is an expected part of the triage nurse's activities, but implementation is variable. Institution Y is an inner-city community hospital, affiliated with an academic center, with an annual census of 48,000; 13.4% are children. Patients at this institution also primarily come from nearby predominantly African American neighborhoods. At the time of the survey, domestic violence screening was not a routine part of the initial patient assessment, but was at the discretion of the health care providers. Institution Z is a suburban community hospital without academic affiliation, with an annual ED census of approximately 74,000; 25% are children. Patients at this hospital primarily come from predominantly white neighborhoods. Intimate partner violence screening questions are on the nurse assessment form and the official policy is that they should be asked of everyone. Implementation is variable.

**Study Protocol.** Two surveys, one for health care providers and one for community members, were submitted for IRB approval to the three institutions. The surveys for the two groups were nearly identical, with differences in demographic questions only (i.e., "What is your profession?—response nurse or physician"; and "What year did you graduate from professional school (MD, RN, etc.)?"). All surveys presented brief domestic violence scenarios followed by questions that sought opinions about screening and benefit of various sources of help. In addition, the questionnaires were designed to be confidential, anonymous, and self-administered.

No questions or answers would have identified a respondent as a victim of IPV.

**Measurements.** The main measurement was the number of business days (Monday through Friday, excluding legal holidays) from the date of initial submission to date of the final approval letter (inclusive).

## RESULTS

The same research protocol and survey instruments were submitted in early October 2001 to all three institutions; the review process, duration of review, and results of the review in particular were inconsistent (Table 1). The study was identified as minimal-risk at all three institutions.

At institution A, the IRB is a centralized committee for four hospitals, which meets on a monthly basis. Membership on the 25-person committee includes physicians, nurses, a member of the clergy, a lawyer, community members, a pharmacist, other individuals with advanced degrees, and an institutional resource person. The protocol underwent expedited review and was approved within 15 business days without revisions. The need for written informed consent was not waived.

At institution B, the IRB is a nine-member panel composed of five physicians, an attorney, a community representative, a member of the clergy, and a pharmacist. The protocol was reviewed and approved within 12 business days without revisions. No expedited review was given, because this IRB expedites reviews only for urgent experimental treatment. The principal investigator was encouraged to attend the IRB meeting. The need for informed consent was waived.

At institution C, the protocol required three revisions and 77 business days prior to final approval. There are two IRB committees, which meet on alternate weeks, and the exact committee composition is confidential. Though the study was formally identified by the IRB as minimal-risk, expedition of the IRB review was not allowed. Each

TABLE 1. Summary of Process Differences between Institutional Review Boards (IRBs)

|  | IRB A      | IRB B         | IRB C       |
|--|------------|---------------|-------------|
| Date of original submission                  | October 12 | October 22    | October 4   |
| Date of approval letter                      | November 1 | November 6    | January 28  |
| Number of working days for final approval    | 15         | 12            | 77          |
| Frequency of IRB meeting                     | Monthly    | Monthly       | Weekly      |
| Consent waiver                               | No         | Yes           | No          |
| Risk level                                   | Minimal    | Minimal       | Minimal     |
| Principal investigator present at IRB review | No         | Yes           | No          |
| Expedited                                    | Accepted   | Not available | Not offered |
| Number of revisions required                 | 0          | 0             | 3           |

revision generated new and different questions or criticism. The first review raised questions concerning the purpose of the research, the methodology for selecting participants, and procedural issues in participating (Table 2). The second review raised concerns about the appropriateness of doing survey research on individuals in ED waiting rooms, ensuring confidentiality, and a request for background literature to assure that the research questions had not already been answered. The third review raised new questions concerning study methodology, sample size justification, and concerns related to the statistical approach.

## DISCUSSION

All three institutions ultimately accepted the research survey, and all three identified the research as a minimal-risk project. However, there were significant inconsistencies in the approaches of the three IRBs as well as the changes that were required before final approval. Though some variability in IRBs may be necessary to reflect cultural beliefs specific to a given area as well as institution-specific concerns, these IRB reviews were all done in the same metropolitan area. The inconsistencies in these reviews raise questions as to the validity and the efficiency of the IRB process. In scientific experiments, while a certain amount of variability (i.e., random error) is likely to occur, too much random error or nonrandom error will affect the reliability of the process and may lead to an invalid conclusion. Validity can be defined as the "extent to which any measuring instrument measures what it is intended to measure."<sup>6</sup> It is important that the IRB process can reliably measure with adequate validity the degree of safety of scientific experiments in order to preclude harm to subjects. Within legal circles, while there is some variability in interpretation of laws, the Supreme Court ultimately sets the standards as to how much deviation from the norm is acceptable. Variability in the IRB process, in and of itself, is not a problem. Too much variability may be, and may lead to decreased research due to increased barriers and expense in attempts to extend the horizon of general knowledge.

While IRBs are mandated to protect human subjects, most attempt to balance the protection of subjects, institutions, and investigators with the benefit to society of allowing medical research to proceed.<sup>7</sup> Excessive inconsistency between IRBs implies that the fulcrum position for this balance reflects institutional politics rather than societal benefits.<sup>5,8</sup> Understandably, IRBs have become more conservative, considering recent Office for Human Research Protection sanctions at major research institutions.<sup>9</sup> Al-

**TABLE 2. Revisions Requested by One Institutional Review Board (IRB)**

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|---|
| <p>First submission (IRB meeting 10/18; letter dated 11/05)</p> <ol style="list-style-type: none"> <li>1. Purpose/goal of the research vague. "If it is not clear how the opinion of someone who is not a victim of IPV* will shed light on the expectations of a victim of IPV."</li> <li>2. Revise consent form to "clearly indicate that information is being sought about expectations of healthcare workers and patients regarding the needs of victims of IPV."</li> <li>3. Clarify how investigators plan on selecting subjects; specify how patients will be approached.</li> <li>4. If the participant turns out to be a victim of IPV, how will this be addressed? Is there a reporting requirement?</li> <li>5. Revise the research project notification (RPN) form to include the completion of the questionnaires.</li> <li>6. "If the subjects sign consent forms, how does the principal investigator plan to ensure anonymity?"</li> <li>7. The right-to-withdraw section of the consent forms needs to be revised to indicate that the participant cannot withdraw after the questionnaire is turned in, since it is anonymous.</li> <li>8. Request for clarification of the purpose of specific demographic questions.</li> </ol> <p>Second submission (IRB meeting 11/15; letter dated 11/20)</p> <ol style="list-style-type: none"> <li>1. "The Committee feels that the targeted subject population (ER patients or their companions) is inappropriate (to be recruited for research or participating in research) because it may place additional burdens on an already burdened population."</li> <li>2. "In addition, the Committee feels that the PI† did not provide sufficient safeguards to ensure confidentiality given the setting (emergency department) in which the research would be conducted."</li> <li>3. Request for reference literature to assure that the questions posed have not already been answered.</li> <li>4. "With regards to subject selection, the absence of a discussion of the reasons for the selection of this subject population, both the scientific validity and the ethical advisability of the elected population is questionable."</li> </ol> <p>Third submission (IRB meeting 11/29; letter dated 12/14)</p> <p>Project received a "favorable review." Additional comments/revisions:</p> <ol style="list-style-type: none"> <li>1. No justification for the need to do the research at three sites. Recommendation that the research only be done at IRB C site as a pilot study.</li> <li>2. Request for justification of sample size.</li> <li>3. "Have the questionnaires been employed in other studies?" "Have they been validated?"</li> <li>4. Revise the consent form to explicitly state that appropriate services and resources on domestic violence will be made available upon request.</li> <li>5. "Note that this protocol qualifies for expedited review. Even on this third review of the protocol by the IRB, the overall quality of the submission particularly the sections detailing the statistical approach and study methodology is poor. If these sections had been better written, the initial reviews of the protocol would have been performed in an expedited fashion."</li> </ol> |
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\*IPV = Intimate partner violence.

†PI = principal investigator.

though most adverse research events have been related to interventional studies, all studies are now being scrutinized more closely.

Few data have been published about the intra-

mural consistency of IRBs; however, one IRB found its process inconsistent enough to review it, establish protocols, and publish a description of the review process.<sup>10</sup> Extramural inconsistency has been documented in association with multicenter randomized control trials.<sup>4,5</sup> While there are arguments both for and against regionalization of IRB review for multicenter trials, review on this scale may not be practical or appropriate for small observational studies. Given the need to promote minimal-risk research projects, a standardized approach, ideally based on national guidelines, to improve IRB consistency and facilitate approval of these low-risk studies may be useful. This approach may take several forms, including a separate (or expedited) review process for minimal-risk studies as well as having the principal investigator present at the time of review. The presence of the principal investigator could streamline the process by allowing misconceptions or misunderstandings to be resolved at the time of review, rather than through multiple communications written over a prolonged period; however, this approach may be problematic at high-volume research institutions.

### LIMITATIONS

This is a descriptive study that involved three hospitals in one metropolitan area rather than a nationwide sample. While regional variability may exist, the IRB process appears to be idiosyncratic to each institution. Based on our experience with three different types of institutions, it is likely there is tremendous variability across the country. Additional research is needed to develop and evaluate potential solutions such as expedited review or protocol development.

Recent studies, combined with our experience, raise an important question that needs further research: what is an appropriate outcome measure in evaluating the IRB process?

### CONCLUSIONS

Institutional review boards have an obligation to protect subjects, ideally without unduly inhibiting the advancement of medical knowledge. Studies that meet predefined minimal risk should not be subject to excessive time delays. Our experience suggests a need for standardization of the minimal-risk review process to decrease variability and therefore improve the validity of the process. Variability, in and of itself, is not a problem. Too much variability may be, leading to decreased research productivity due to the increased barriers and expense of inconsistent review.

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