

Best Precedents in Human Subjects Protection for Health Services Research

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OBJECTIVES: The objective of the proposed study is to identify the “best precedents” for a number of human studies issues in health services research. These precedents could be referenced by VA investigators as they prepare IRB applications and by members of human studies committees and university institutional review boards as they seek to rule on these issues at the local level. The precedents would not supplant the local committees’ and boards’ review process or decisions, but would offer them guidance in areas where none or very little presently exists.

RESEARCH PLAN: The study plan is a cross-sectional, observational design with primarily qualitative analyses.

METHODS: Multi-site health services research studies initiated since 2001 were identified from several sources: (1) a list of multi-site studies obtained from VACO HSR&D Service, based on data from the HSR&D Annual Report database; (2) an e-mail request sent to associate directors of all HSR&D Centers of Excellence; and (3) word-of-mouth. A total of 50 studies were identified from these sources. Following human subjects approval at the Ann Arbor VAMC, e-mails were sent to the PIs of all of these studies requesting a copy of the original protocol, IRB application material for each participating site, and all IRB correspondence/approvals for each site. A total of 46 PIs or project managers responded to this initial request, and no PIs refused to participate. The requested material was received from 42 studies. Of these, 27 were determined to be appropriate for inclusion. The study material was reviewed to determine common issues across the studies for which IRB responses varied. (See “Findings” below.)

Following identification of the list of IRB issues, a series of case studies will be developed to illustrate each issue, along with a description of the different decisions made by IRBs for each issue. An expert panel will be formed, consisting of IRB experts, ethicists, health services researchers, and a patient representative, who will review the case studies and select the best precedent among the actual responses. If the panel members do not consider any of the responses to be appropriate, they will be asked to give their own response. They will also be asked to provide a brief explanation of their rationale for their choices. Documentation of relevant federal guidelines, and interpretations by various national organizations, will be provided to assist in their review.

The responses of each member will be compiled and summarized, and a series of teleconferences scheduled to discuss differences in opinions among panel members, with the goal of reaching consensus (if possible) on each issue. We are planning to complete and distribute the case studies in November, with teleconferences to be held in December.

The resultant best precedents will be assembled in a document and Web site, for dissemination to IRBs and investigators.

FINDINGS. Of the 27 studies reviewed, the mean number of sites/study was 7.1 (range of 2 to 43). Studies were about evenly split between observational (13) and intervention (14). All of the interventions are primarily related to the organization of care delivery, and not to any major treatment changes. They include such things as case management, educational interventions, intensive referral efforts to a particular treatment, implementation of evidence-based care, reminders, and phone calls to patients. Review of the IRB material identified the following 10 issues that occurred in more than one study, and for which IRB responses varied:

of Studies IRB Issue

16	Discrepant reviews (full, exempt, expedited)
6	Differences of opinion regarding use of waiver/consent form
4	Inclusion of irrelevant consent language (including HIPAA)
4	Differences in training requirements
3	Recruitment strategies (using databases)
3	Identification of suicidal patients, undiagnosed conditions
3	Provider incentives
2	Identification of vulnerable subjects (including employees) and precautions
2	Consent language--description of risks
2	Notification of unions

Not included in the above table are issues related to changes in wording of consent forms, and lack of standardization of requirements across sites, which were issues in every study.

Next steps include formation of the expert panel and development of the case studies to coincide with the issues above.