Accreditation Helps Researchers and Subjects Alike

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One of the least understood areas of human research protection is the application of federal regulations for protecting subjects who participate in behavioral and social science research. I would like to address two widely held beliefs: that federal regulations are not applicable to behavioral and social science research, and that, when applying them to behavioral and social science research, IRBs often over-interpret the regulations.

The behavior of IRBs is driven by several factors. First, the federal regulations are written from a clinical perspective. Take, for example, one of two criteria for waiving documentation of consent: “That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.” While this criterion is perfectly understandable in a clinical setting, it lacks meaningful definition for research conducted outside of a physician’s office or hospital environment.

Second, IRBs, in light of the suspensions of major research programs between 1991 and 2001, have followed the lead of their institutions and become adverse to risk. It is safer for the institution (not necessarily for the subject) to use full board review rather than exemptions or the expedited review process, to require an informed consent process with all elements of disclosure even if some are irrelevant, and to fully document the process.

Third, there is virtually no federal guidance on how to apply the regulations to behavioral and social science research. Thus, IRB members and investigators are left feeling frustrated; investigators question the credibility of the protection system and try to find ways around it.

The ethical principles that govern the conduct and review of research are the same for all research types. The basic principles of respect for persons, beneficence, and justice are relevant. In a psychological experiment involving students, an anthropological study observing indigenous tribal persons, or a secondary analysis of existing identifiable data in economics, investigators must respect individuals as human beings and protect their rights and welfare.

But the standard for achieving these ethical principles, I would argue, differs according to research type. And this is where the problem lies. The federal regulations, which for all intents and purpose are the ethical standards, must be interpreted appropriately for different types of research.

In behavioral and social science research, there is both over- and under-interpretation of the regulatory requirements. For example, some research determined to be exempt does not fall into any of the allowable exemption categories. On the other hand, some IRBs do not use exemptions at all. While the latter is an IRB’s prerogative for research involving little, if any, risk, the potential exists for resources to be misdirected unnecessarily. The burden on investigators to comply with the IRB process, even though there is little added protections value, undermines the IRB system. The same is true when the

expedited review process is forfeited for full board review.

Concerns are consistently raised about IRBs requiring lengthy, overly involved informed consent processes. IRBs are reluctant to remove irrelevant elements of disclosure from the consent process because of the difficulty invoking the four criteria for alteration. It is far easier to require the scientist to include the information in the consent document or in the verbal transcript to prospective participants. Likewise, IRBs are reluctant to waive documentation of the consent process – why waive it if the scientist can get a signed written consent?

Beyond the problem of frustrating investigators, or undermining the integrity of the protection system, the real issue is that participants may not be receiving the best protections. Raising concerns about irrelevant issues-such as alternative treatments when the study involves no interventions or stating that there will be no loss of benefits-can unduly alarm participants. The informed consent process and its relevant documentation must be appropriate to the methods, risks, and potential benefits involved in the specific research study under consideration.

For most behavioral and social science research, threats to privacy and confidentiality are the primary risks. Yet the nuances of these potential harms is often misunderstood or overlooked. Privacy interests refer to the ability to control access to one's person and/or information about one's self. Obtaining informed consent is necessary in respecting privacy but is not sufficient. Scientists and IRBs must take into account the methods used and the contexts in which information is obtained. Likewise, confidentiality is complex and involves informing research participants about plans for sharing identifiable data with other investigators or interested parties, the extent to which confidentiality is protected by law, and how identifiable data will be handled.

One effort that addresses how organizations, IRBs, and investigators handle protection in behavioral and social science research is accreditation by the Association for the Accreditation of Human Research Protection Programs, Inc.® (AAHRPP®). AAHRPP offers voluntary, peer-driven, educationally based accreditation to organizations that conduct or review research involving human participants. The interests of behavioral and social scientists permeate all aspects of AAHRPP. The Consortium of Social Science Associations is one of seven founding members, behavioral and social scientists sit on both the Board of Directors and Council on Accreditation, and they participate as site visitors.

AAHRPP's Accreditation Standards address the protection issues mentioned previously. By using an educational and collegial approach, site visitors and the Council on Accreditation advise organizations about their interpretation and implementation of the federal regulations, specifically in behavioral and social science research. Further, they look beyond the regulations to ethics standards within research disciplines and evaluate whether investigators follow such guidance.

Accreditation has the potential of improving protections for research participants by bringing uniformity in protections to a wide variety of research types. Through the consistent application of its Accreditation Standards and the sharing of best practices, AAHRPP accreditation will help deter both over- and under-interpretation of the federal regulations. Consistency across IRBs in the interpretation and use of exemptions and the expedited review process, for example, should lead to a level of protection that is commensurate with the level and nature of risks involved. Using informed consent processes that are relevant and meaningful to the research participants will go a long way toward respecting them as

autonomous individuals. Finally, identifying and minimizing risks associated with behavioral and social science research, particularly threats to privacy and confidentiality, will make research safer.

Accreditation can certainly help to improve protections for research participants, but it can also help to reduce investigators' frustrations and increase the credibility of the research protection system.