"Outlaws, In-Laws, Crooks and Straights": Regulations, IRBs and the Need for Evidence-Based Protections in Survey Research

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Abstract

"Outlaws, in-laws, crooks and straights" are among those that the Common Rule for the Protection of Human Subjects (34 CFR 97) and other privacy protections are designed to protect us from.[2] Proliferating data sets that can be linked to a target survey and improving software are making it ever more likely that intruders can penetrate data confidentiality protections. At the same time, work to improve public and private policy outcomes through use of evidence-based policy and performance monitoring makes data access and use ever more important for reducing risks and improving outcomes. This presentation examines the role of evidence-based protections in survey research.[3]

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How can we ensure adequate protection of privacy in survey research while maximizing the appropriate use of this data? Having dealt with these issues as a consumer of research (e.g. university teacher, Congressional staffer), as a researcher (at Institute for Social Research, and as an evaluator for the US Department of Education) and as a regulator of research (as protection of human subjects coordinator at the US Department of Education, and participant in interagency groups on human subjects protections and data confidentiality and access), I bring diverse experience to this issue. I am particularly interested in how to achieve effective protections without creating unnecessary barriers to valid and reliable research. As a panelist, I'll discuss why good intentions and "a culture of compliance" are not enough and sketch a strategy for moving toward the efficient frontier of effective protections and valid research.

My fellow panelists have focused on national statistical surveys. While I deal with such studies, much of my work deals with smaller studies that often link survey data to administrative records or other information. These studies can directly affect hiring and firing, and reputations of individuals, as well as the creation or termination of programs. With the stakes so high, these studies illustrate how volatile survey research, whether stand-alone or as part of a broader study, can be—drawing the attention of parents, advocacy groups, media, Congress, and the courts. Even a few outliers with problems may have large impacts on how the public and policymakers perceive survey research, and on public willingness to participate in studies.

Some problems arise from inadvertent noncompliance. Respondents, researchers, regulators and others are sometimes not aware of all the applicable statutes, leading to inadvertent noncompliance. In addition to statutes governing national statistical agencies, studies may be covered by the Protection of Pupil Rights Act (PPRA), the Family Education Rights and Privacy Act (FERPA), the Health Insurance Portability and Accountability Act (HIPAA) and/or other laws. Many are covered by the Common Rule for the Protection of Human Subjects in Research, which has been adopted by 17 US agencies (34 CFR 97).

When regulatory procedures create barriers to achieving unbiased samples of adequate power, they can create serious unintended consequences for the study, for taxpayers and for all affected by how the flawed data are used to (mis)inform policy and practice.

Limits on data collection and use must be balanced by the need for high quality data to inform policy and practice. There is a growing movement to shift from fad-and tradition-based practice to evidence-based practice.[4] However, in many policy areas we often know less than we think we do about "what works" (and what doesn't). An analysis of every article published in American Education Research Association's *Educational Research Journal*, and *Educational Evaluation and Policy Analysis* from 1993-2002 found that only 6% utilized a randomized trial as primary research method. Even adding studies with matched comparison groups only brought the total to 16%. Similarly, a study of "school-wide reform" models by AIR found few had

systematic evidence of effectiveness. Similarly, in health care, a recent *Business Week* cover featured a wheel-of-chance listing treatments with the headline: "Medical Guesswork". The article reported that studies to establish the safety and effectiveness of many common treatments have never been conducted.

When it comes to protection and the protection of human subjects (including privacy protection), it too often seems to approximate an "evidence free zone" with little systematic information to help us assess risks and to identify effective protections. For example, an Office for Human Research Protections (OHRP/HHS) compliance letter to University of California at Berkeley and Lawrence Livermore Laboratory raised concerns that researcher's repeated efforts to get nonrespondents to return a survey could pose issues of coercion--in violation of the Common Rule.[5] There appears to be little empirical information about what procedures potential survey respondents perceive as "coercive"—or on how to balance this concern with the need for adequate response rates in order to have a valid and reliable study. Similarly, Institutional Review Boards (IRBs) often raise concerns that surveys and interviews with victims of sexual or spousal abuse will traumatize the respondents—and may require major changes in the study design or may forbid the study. However, the available research suggests that many respondents do not find such studies troubling and some appreciate the opportunity to discuss their experience in a confidential setting. Many IRB reviews require changes in informed consent forms—but analyses of IRB-approved informed consent forms find that the IRB inspired changes often result in informed consent forms that are excessively long, complex and not understood by many study participants. One article's title summed up the situation: "Does anybody read these things?"

This lack of evidence-based practice becomes particularly problematic in large multisite studies where IRBs often disagree about risks, informed consent procedures and other study elements. The resulting delays, burdens, and inconsistencies across sites can bias samples and/or make it difficult and in some cases impossible to conduct large scale studies. We need to improve the knowledge base on study risks and effective protections. Study design and field procedures are likely to play important roles in minimizing or eliminating such risks—but this is a matter of evidence, not of mere opinion. "Because I said so!" should not be the regulatory standard in protection of human subjects.[6] We need to move beyond anecdotes, tradition and a "culture of compliance" in protecting human subjects to evidence-based protections. While as this panel has pointed out, we need to do more than the minimum required by law, even with the best of intentions, "going beyond the law" is not always a good idea. In the example above, well-intentioned IRBs can make it difficult or impossible to do some studies. We need to move from review based on first principles, speculative risk and anecdotes to include evidence of how to effectively protect human subjects while not needlessly harming the ability to conduct valid studies. This requires empirical studies of risks and effective protections in survey research.

While we are "in need of further empirical research" (I.N.F.E.R.), on privacy protection and other issues in protection of human subjects, there are islands of evidence that we can use and build on—to improve the protection of human subjects in research. This includes large and growing research literatures on survey nonresponse and the impact of field procedures (including informed consent procedures). Federal agencies have funded some important work in this area, including US Census funded work on attitudes toward confidentiality and participation in survey research (e.g. work by Eleanor Singer), and work on confidentiality protections (such as that funded by NICHD). To make this existing knowledge base accessible, we need to inventory the existing research on protection of human subjects, catalog current and planned research on research, strengthen networks among those who work in this area which is currently islands of isolated specialists, and develop the research syntheses, clearinghouses, decision tools and networks to translate the emerging knowledge into better protection of human subjects.

Professional organizations, such as the A.S.A., can play a important role. As members of IRBs and data safety monitoring boards, statisticians can draw attention to where better information is needed on risks and effective protections. In designing and conducting or advising on the design of studies, they can encourage the conduct of studies—either free-standing or as modules in larger studies—to provide credible assessments of research risks, and on the

effectiveness of various procedures for study recruitment, informed consent procedures, confidentiality protections etc.

For businesses and venture capitalists, there is a need to develop and sell the tools to transform the emerging knowledge base into robust decision tools for researchers, IRBs and others to use in designing, conducting and reviewing studies. This could include tools to better incorporate assessments of the risks of research into IRB and regulatory decisions. Recent experience in other fields suggests that considerable progress can be made here. These include current work to reduce and eliminate medical accidents, increase the safety of transportation, and improve workplace safety.

In addition to the islands of evidence and opportunities ongoing work noted above there are other hopeful signs. The emergence of protection of human subjects in research as a professional field includes the recent creation of the *Journal of Empirical Research on Human Research Ethics (JEHRE)* to supplement the other largely qualitative work on research ethics. PRIM&R, the leading professional association of IRB members and others involve in the protection of human subjects has announced that its annual November conference will include a major panel on "*From anecdotes to evidence: How IRBs can use evidence-based practice for more effective protection of human subjects*". These are only seeds of change, but they auger well. I look forward to working with fellow members of the American Statistical Association and others for the development of the field of evidence-based protections of human subjects -- to move us toward the efficient frontier of effective human subjects protections and rigorous scientific studies to improve policy and practice.

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[1] The author is protection of human subjects coordinator at the US Department of Education. This presentation is intended to promote the exchange of ideas among researchers and policy makers. The views expressed in it are part of ongoing research and analysis and do not necessarily reflect the position of the U.S. Department of Education.

[2] The title draws on Brooks and Dunn's lyrics in "Boot Scoot Boogie".

[3] See National Research Council (2003) *Protecting Participants and Facilitating Social and Behavioral Sciences Research*, and (2005) *Expanding Access to Research Data: Reconciling Risks and Opportunities*, Washington, D.C.: National Academies Press.

[4] See, for example, the Cochrane Collaboration http://www.cochrane.org/ for health-related research, and the Campbell Collaboration http://www.campbellcollaboration.org/. The cited issue of *BusinessWeek* is May 29, 2006. See also Report of the Coalition for Evidence-based policy: *Bringing Evidence-Driven Progress to Education* (Nov. 2002). http://coexgov.securesites.net/admin/FormManager/filesuploading/coalitionFinRpt.pdf

[5] Office for Human Research Protections (OHRP) at HHS: OHRP Compliance Oversight Coordinator to University of California at Berkeley and Lawrence Livermore National Laboratory, Dec. 3, 2002.

[6] See for example, the Information Quality Act (IQA), sometimes referred to as the Data Quality Act, which was enacted in December 2000 as Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (P.L. 106-554).