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Hidden Data for Research Ethicists: An Introduction to the Concept and A Series of Papers

James M. Dubois

Saint Louis University

Abstract

This special section of the *Journal of Empirical Research on Human Research Ethics (JERHRE)* is based upon the assumption that much of the best empirical data relevant to research ethics is hidden from the view of Research Ethics Committee (REC) members and others who are interested in research ethics. There are at least three different senses in which ethics-relevant empirical research may be hidden: (1) it may be published in a journal that ethics committee members would not regularly read, (2) it may not use key words that would guide one to its ethics-relevant content, or (3) it may be sequestered in part of a research article that is about something else. This special section of *JERHRE* reviews all of these types of “hidden ethics” articles on the following issues: What is the relative frequency of hidden ethics articles in journals that focus on vulnerable populations? What does the non-ethics literature in clinical research and experimental economic decision theory teach us about ways of improving subjects’ comprehension of risk information? How satisfied are parents and children with their experience with pediatric psychotropic medication trials? And, how can retention rates be improved in longitudinal studies of difficult regimens such as drug rehabilitation? There is a major amount of ethics-relevant literature that is hidden. Without better ways of communicating the existence of this literature through use of key words, or recasting of the information to highlight its relevance to research ethics in journals that ethics committee members read, the benefits of evidence-based ethical problem solving will be lost.

Keywords

research ethics; review article; institutional review boards; human experimentation; vulnerable populations

This special section of the *Journal of Empirical Research on Human Research Ethics (JERHRE)* examines empirical data relevant to research ethics that are hidden from the view of Research Ethics Committee (REC) members and others who are interested in research ethics. In the weakest sense, an article is hidden if it is not published in a journal that REC members might regularly read, i.e., a journal that has a special focus on research ethics or evidence-based ethical problem solving (such as *Accountability in Research; Ethics and Behavior; IRB: Ethics & Human Research*; and now *JERHRE*). A second, deeper sense in which an article may be hidden is that it does not include any keywords or subject headings that pertain to research ethics. Examples of such keywords include: “research ethics” or “research” combined with terms like “informed consent,” “confidentiality,” “justice,” and “conflicts of interest.” If articles neither appear in a journal dedicated to research ethics nor are indexed using keywords related to research ethics, then they will indeed be hidden from the view of most REC members, even those who search the literature using databases such as MEDLINE or PsycINFO. Finally,

the deepest sense in which empirical data that are relevant to research ethics may be hidden occurs when the authors of the study themselves either do not recognize or do not explicitly discuss the ethical significance of their findings.

One might wonder how could authors fail to notice that their own study produced ethically significant results. Turiel (1983), Nucci (2001), and others postulate that one and the same event may be approached through different domains of reasoning. Ethical or “moral” reasoning is activated when actions are seen as have interpersonal consequences involving harm, personal welfare, and fairness—concepts related to the Belmont principles that were developed to guide the ethical review of human research (National Commission, 1979). Other social domains of reasoning include the conventional and personal. But in principle one may approach an interpersonal problem entirely from outside the social domain, treating it as a technical or quantitative problem. This is why it is not nonsensical to ask, “Is a decision to randomize participants to experimental conditions a technical or an ethical decision?” Insofar as a decision to randomize may be seen to affect both the scientific rigor of a study and the well-being of participants, it is both technical and ethical. Such decisions are likely to be seen as ethical decisions only when one actually fears that randomization will cause harm. That is to say, we may not view specific research decisions as ethical decisions unless something triggers the moral domain of our reasoning. Nevertheless, data on randomization that are presented as technical or medical may be of great ethical importance. For example, data indicate that those participants with major depression who are randomized to receive a placebo actually have lower rates of suicide and suicide attempts than those randomized to receive an investigational medication or an active comparator—a finding opposed to what some REC members might fear when a known effective treatment is withheld from someone with a serious disorder (Khan, Warner, & Brown, 2000). While the article by Khan et al. specifically investigated the ethical question of randomization to placebo, most of the individual studies they reviewed did not; they merely presented scientific, medical results in a neutral fashion.

The four papers in this Special Section of *JERHRE* explore various dimensions of hidden research ethics; that is, they systematically review empirical literature that is largely obscured from the view of REC members for one reason or another.

The first article by DuBois, Volpe, and Rangel reviews all articles published from 2005 through 2006 in three leading journals that focus on research with vulnerable populations: *AIDS*, *American Journal of Psychiatry*, and *Pediatrics*. The aim of this review is to explore the prevalence of hidden empirical data pertaining to research ethics using a purposive sample of the literature. Drawing from the taxonomy of the requirements of ethical research provided by Emanuel, Wender, and Grady’s (2000) review of international codes of research ethics, the authors determined that the three journals contained at least 26 articles with ethically significant findings. Only 7 articles contained keywords clearly related to research ethics, while 12 articles used related keywords (such as “recruitment” or “research methods,” which would relate to the ethical requirements of “fair subject selection” and “scientific validity”); 15 of the articles contained no discussion of the ethical significance of their findings. The authors explore the implications of these findings for the composition of RECs, the training of REC members, and the ethical review of research. They observe that researchers should not assume that REC members are familiar with the empirical data that would provide an evidence base for appropriate research protections and consent procedures. Rather, researchers should be familiar with the empirical literature in their fields and share their knowledge with REC members in ways likely to be accessible to REC members.

Each of the remaining three articles explores specific questions in research ethics by drawing on empirical literature that is scattered across scientific journals. They are of interest not only insofar as they illustrate the importance of discovering *hidden-ethics* research, but also in their

own right as they review literature that can answer significant questions that REC members must consider.

Anderson and Iltis (this issue) observe that if free and voluntary informed consent requires the disclosure, understanding, and appreciation of risk information, then we should ask whether there are effective ways of assessing risk comprehension and improving risk communication. They review over 60 publications on risk communication and comprehension—primarily articles found in clinical, medical literature, and some closely allied literature from experimental economics—extrapolating lessons for researchers and REC members. Among their key recommendations: Researchers should avoid using vague descriptors, such as “low” or “high” risk; and researchers should present data on risks in a variety of formats, for example, using verbal and printed numerical information or graphs accompanied by numerical explanations.

In 1995, Michael Aman and Patricia Wolford published what appears to be the first “customer satisfaction” study of parents who enrolled their children in a clinical trial (Aman & Wolford, 1995). In this issue, together with Cristan Farmer, Michael Aman reviews the empirical literature on participant satisfaction and the informed consent process in studies involving psychotropic medication with children and adolescents. Once again, we find that an important body of literature on matters of research ethics exists primarily outside of ethics journals. Their review indicates that parents and their participating children generally have good knowledge of the purpose of trials, experimental conditions, the possibility of receiving placebo, and their right to withdraw from a trial. Surveys that investigate participants’ satisfaction with studies generally indicate high levels of satisfaction with the choice of outcome measures, the clinical recommendations emanating from the research, and the treatment they received. The vast majority of participants indicate that they would recommend similar studies to other parents and children who meet inclusion criteria. It appears that an important reason for satisfaction with their participation in clinical trials, irrespective of whether they receive the medication or are placebo controls, is the information and clarification that parents and children gain about the child’s problematic behavior.

In 1996, Linda Cottler and colleagues published a paper reporting a 96.6% retention rate in a longitudinal study of drug abusers (Cottler, Compton, Ben-Abdallah, Horne, & Claverie, 1996). While the original publication appeared in a manner inaccessible to most people doing research ethics, the authors were well aware of the ethical implications of their study: individuals who abuse drugs are often routinely excluded from research for reasons of inconvenience and not for the alleged reasons of scientific infeasibility; that is, it is assumed that they will not be compliant and are likely to drop out. More recently, Linda Cottler’s working group has begun investigating the relationship of study retention to participant values and goals. The paper in this issue by Striley, Callahan, and Cottler presents the original research of their working group through the lens of the principles of justice and beneficence, introducing it to a new audience of readers.

Together these papers suggest that a significant amount—if not the overwhelming majority—of literature relevant to the ethical conduct of research is potentially hidden from the eyes of REC members for a variety of reasons. When agencies such as the National Institutes of Health fund the collection of data on research ethics, or when researchers publish data relevant to evidence-based ethical problem solving, they may hope that their data will lead to improvements in the conduct of human research and REC practices. These papers suggest that such hopes may be dashed if we do not find more effective ways of communicating that such data exist.

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Biography

James M. DuBois is the Hubert Mäder Endowed Chair and Department Chair of Health Care Ethics at Saint Louis University. He also directs the Center for Clinical Research Ethics within the Institute for Clinical and Translation Sciences at Washington University, St. Louis. His current research interests include mental health research ethics, ethics program evaluation, and organ transplantation.