Evidence-based Ethical Problem Solving: A Research Agenda

The most fascinating aspect of this 30-year “experiment” is that no one has bothered to collect data to demonstrate that there ever was a bona fide need for such [IRB] reviews to begin with (Mueller & Furedy, 2001a, 2001b), nor has anyone collected data to document that the regulations have actually protected human subjects or improved the subject’s research experience. (Abbott & Grady, 2010)

The costs of [research] fraud for the careers of young scientists … for science, and for public trust in science are devastating…. [T]he moment is opportune to reflect on what can be done to protect science and the public from fraud in the future. (Crocker & Cooper, 2011)

Whether the issue is the effectiveness of IRBs, ways to deter scientific fraud, or any of the many other ethically relevant questions about human research, our science will advance as we learn to formulate these as testable empirical questions and engage in evidence-based ethical problem solving—in other words—do research on research ethics. Human research is improved when we scrutinize our methods. There are many kinds of ethics-relevant issues that can be elucidated through empirical research. These issues might be divided roughly into four main categories, each with a set of subcategories somewhat as follows—all topics that you will recognize from discussions in the preceding chapters.

Communication issues: recruitment, informed consent, deception, relationships as a source of data (e.g., ethnography), community-engaged research, language and meaning across cultures and contexts.

Acquisition and use of data: privacy, confidentiality, use of data.

Risk and benefit: risk, wrong, and harm; benefit, incentive, promise of social value; risk-benefit assessment.

Other influences on research: ethics research committees; other institutional influences; perceptions that influence research and ethical problem solving; questionable, taboo, and controversial topics of research; scientific integrity and responsibility; ethics and politics; human research literacy; new technologies creating new methods.

Obviously, these categories are not exhaustive, nor are they mutually exclusive. For example, the topic of
direct concern to you might be the way your institution and IRB responds to many of the protocols that come before it. The problems might concern some of the IRB’s requirements for informed consent that bias one's sampling or IRB concern about risk to confidentiality that you believe is unrealistic. Note that these IRB concerns have spanned all four main categories of concern.

**Are You Interested in Doing Evidence-Based Ethical Problem-Solving Research?**

We hope we have whetted your appetite for human research and sensitized you to the importance of recognizing, understanding, and resolving ethical issues involved. We have sought to demonstrate, by the literature we cite, that much of what we understand about how to do ethically responsible research is based on empirical evidence and that many outstanding researchers have conducted and published studies that provide evidence for ethical and methodological best practices in their research. There are now several entire scientific journals dedicated to publishing evidence-based ethical problem-solving research. If you are a graduate student, there are many eminently researchable topics you might want to undertake as a master's or doctoral project. If you are an IRB member or administrator, you too should be collecting data on what works and what doesn’t. And if you are an established researcher, you will find that you can often advance your specific research approaches by examining them empirically.

**Sources of Research Ideas**

Typically, the best research ideas grow out of your own concerns and interests. The reflective questions at the end of each chapter have probably evoked researchable questions in your mind. Most of one’s own research projects evoke questions about ethics. Any review of the literature on ethical issues will ultimately lead you to new questions that remain unanswered. There is, however, another major source of empirical questions. The *Journal of Empirical Research on Human Research Ethics (JERHRE)*, which is published five times a year, is the major publisher of evidence-based ethical problem-solving research. In July 2006, *JERHRE* held a conference to explore the key empirical questions that needed answering, the results of which are published in the March 2007 issue of *JERHRE*: 65 pages of research agendas focused on diverse topics such
as trauma research, mandatory reporting, cultural competence, deception, data sharing, cultural competence of researchers, and educational research. Further, each article in every issue of JERHRE concludes with a brief section titled “Research Agenda,” which describes the empirical questions that that article leaves unanswered.

You will find hundreds of research agendas in back issues of JERHRE. If your library does not subscribe to JERHRE, you may wish to download some of its articles from PubMed, or http://www.jstor.org/action/showPublication?journalCode=jempreshumreseth. In the rest of this chapter, we will generate additional research ideas for your consideration.

**Research on Institutional Research Boards and Regulatory Issues**

Because so much of the discussion so far has been about the relationship between researchers and their IRBs, we begin by examining some related research questions about IRBs that are ripe for empirical testing. We suggest kinds of questions that might be appropriate for undergraduate research, MA theses, PhD dissertations, and larger studies by IRBs, research administrators, and investigators. We will then explore some of the other ethical issues that call for empirical study and provide some provocative questions and relevant literature to point the way to some other important and eminently publishable research topics for your consideration.

*Research on IRBs.* Investigators who complain about the failure of their IRBs to understand their particular research methodologies or to respond sympathetically to their protocols are often advised to join an IRB and thus to make it more user-friendly by bringing needed knowledge to its deliberations. Is this assumption correct—can new members make an IRB more user-friendly? Unpacking this simple question reveals many related questions: Why do people join IRBs? What special knowledge do they perceive themselves bringing when they join? Are they able to use that special knowledge in their roles as IRB members? Does the assignment of work within an IRB make optimal use of its members’ knowledge and skills? What do they learn about the IRB process when they become members? Do they feel they have improved their IRBs; if so, in what ways? Do their peers in their discipline feel that they have improved their IRBs or made them more user-friendly? What, if anything, have they concluded about the way IRB members should be recruited and
trained? These sorts of questions could be asked at varying levels of complexity. Persons seeking to research these questions might gain the needed sophistication to effectively formulate appropriate questions and recruit participants by themselves volunteering to serve on IRBs (even undergraduate members are welcomed by many IRBs). Here are three ways one might approach this research problem in order of sophistication and difficulty:

**Simple interview of IRB member:** As a simple project by an IRB chair or director, a student or an investigator could attempt to gain a basic understanding of what new members can bring to an IRB: The researcher might interview the members of an IRB to learn why they joined, what special knowledge they think they brought, how they were able to use this knowledge in their roles as IRB members, and in what ways, if any, they believed they made the process more user-friendly for other researchers. (This project would also make a good undergraduate thesis.)

**Building on the above study idea:** The researcher might develop the interview protocol by first doing some pilot interviews or conducting focus groups with a few IRB members to develop an interview schedule that is appropriate to the project. If the researcher has access to various IRBs that serve different disciplines, a comparison across IRBs would be informative both to establish whether there are generalizations that can be made across discipline groups and to determine what kinds of problems might be specific to given disciplines. This would also make a good master's degree project.

**Building further to create generalizable knowledge:** The researcher might extend this research to various institutions that differ in important ways, for example, the amount of research conducted, the workload of each IRB, the types of research conducted (e.g., biomedical, behavioral, social, demographic, epidemiological). This would be a challenging project for any researcher and an especially challenging dissertation project.

An interesting aspect of these projects, at any level of sophistication, is the problem of IRB approval, access, and informed consent. Researchers will need to use every means available to gain the trust of the IRBs involved and to obtain approval of their protocol. No organization, IRBs included, wants to deal with a researcher who wants to play “Gotcha” with those who are studied. Further, research collaboration with the IRB should be considered, as IRB input to the process will be valuable and will create buy-in so that the IRB members will be motivated to use what is learned. That, in essence, would be a form of CBPR.

**Other kinds of studies of IRB or regulatory issues.** Governments at national, state, and local levels, as well as scientific and professional societies and funding agencies, enact regulations or policies governing human
research. While these may be well intended and appear straightforward, they are subject to diverse interpretations and may have untoward and unanticipated side effects. What are the effects of regulations and policies on research, including the effects of regulations in other countries and on animal research? How can empirical evidence influence the regulatory process?

Other Ethical Issues That Call for Research

Almost any research- or ethics-related topic we mention might be related to IRB and regulatory issues, but we categorize them differently to differentiate them and stimulate your thinking about research topics that might interest you. Referring back to the four main categories of research on research ethics, we now examine those and some subtopics within each. While we categorize topics, there is in fact much overlap among them. For most of these subtopics, we will cite at least one study as an example. All of the examples are articles that have appeared in the JERHRE and are readily available perhaps from your university library or PubMed and always as a reprint from University of California Press. The examples are designed to illustrate some of the methods employed in evidence-based ethical problem solving. In most cases, the research instruments employed in each article are available in an appendix to the article or on a supplementary website for those who wish to replicate or extend that particular study.

Communication Issues

Recruitment. Research recruitment might involve various topics, intermediaries, and technologies. What ethical issues are involved? How is recruitment regarded by potential subjects under various circumstances?

Examples: Brintnell-Karabelas, Sung, Cadman, Squires, Whorton, et al. (2011), who conduct clinical trials at the NIH, examined the reasons why eligible candidates decline to participate in clinical trials. Genetic researchers Beskow, Namey, Cadigan, Brazg, Crouch, et al. (2011) examined how participants respond to being recontacted based on their genotypes for further research to explore correlates with phenotypical characteristics (relating to epilepsy, autism, or diabetes) and also to explore issues of disclosure of individual results.

Informed consent. Research might involve communication processes between the researcher and participant,
organization, or other entity. Study of these processes may include variables such as modes of communication, conditions surrounding the research, cultural and perceptual factors, and their influence on ethics-related variables such as comprehension, trust, decision making, competence, and autonomy of participants.

Examples: Woodsong, MacQueen, Namey, Sahay, Morar, et al. (2006), who conduct research on HIV infection in developing countries, report research in seven countries where the autonomy of women is generally not recognized but where they found a variety of ingenious ways to increase women’s autonomy in deciding whether to participate in microbicides clinical trials. Biomedical researchers Kass, Sugarman, Taylor, Fogarty, Goodman, et al. (2008) report the differences between what researcher-physicians say to participants in oncology trials and what those participants hear.

Deception. Research might involve the study of concealment, mental reservations, intended deception, consent to deceive, placebos, perceived deception, self-deception, use of devices intended to distract participants from the main purpose of an activity in order to evoke spontaneous behavior, and desensitizing and debriefing (de-hoaxing). Many questions may be asked about the effects of deception, debriefing and desensitization, participants’ perception and evaluation of deceptive methods, and the efficacy of alternatives to deception.

Example: Psychologists Oczak and Niedzwieriska (2007) report an educational way to debrief subjects of deceptive research by teaching them how to increase their abilities to detect deception in everyday life.

Relationships as a source of data. Qualitative research typically involves getting to know persons and then reporting on some aspect of their lives. Research might focus on the nature of the relationship as perceived by the researcher, participants, gatekeepers, IRB, or others; how this is related to the way the research problem is defined; how subjects are approached and give consent; how the data are collected and organized; and how participants may be respected or wronged.

Examples: Ethnographers van den Hoonoord and Connelly (2006) examine the effect of ethics review on the use of ethnographic methods by master's degree students in Canada. Cultural anthropologist Cooper (2007) explores ways in which participants in ethnographic research can be harmed by returning the results of the research to the communities that were studied.

Community-engaged research. Investigators may become involved in a subject's community to formulate research that would be optimally useful and acceptable to members of the community and to provide oppor-
tunities for mutual understanding. What are effective ways to fulfill these functions? What are the effects on validity, feasibility of future research at the site, the feelings of the subject and members of the community, and the way the findings are applied?

Examples: Community researchers Silka et al. (2008) address the problem confronting many minority communities located near major research universities—how to create guidelines and community gatekeepers to require local researchers to respect the needs of the community and not simply exploit it in order to reap publications and career advancement. Ross et al. (2010a, b, & c), in a major, three-part series of articles, explore considerations that should guide researchers in translational medicine as they establish relationships with community partners.

Language and meaning How can differences in language and meaning within and between cultures be bridged, yielding ethical procedures and valid and comparable results? Traditional practice holds that everyone should be told the same thing, but more recent study suggests that meaning, not words, should be held constant. What are effective ways to ask and answer questions about meaning?

Example: Sociologist Willis (2006) describes how the technique of cognitive interviewing can be used to determine how to express information (e.g., informed consent statements, research instructions, survey questions) in a way that communicates the intended meaning to members of a given population.

Acquisition and Use of Data

Privacy. This refers to participants’ interest in controlling the access of others to themselves. The need to establish boundaries is manifested differently depending on learning, culture, and developmental factors. Theory coupled with empirical study can elucidate how persons in various cultures, contexts, and stations in life define and orchestrate their privacy and the best ways to understand and respect the privacy of research subjects.

Example: Statistician and demographer Zayatz (2009) reviews resources for assuring the privacy and confidentiality of research participants.

Confidentiality. This refers to limiting access to identifiable data. Under what conditions of confidentiality are
research participants willing to divulge information? How can researchers meet the conditions of confidentiality that they promise? What are effective ways to reduce threats to confidentiality?

Example: Catania, Wolf, Wertleib, Lo, and Henne (2007) report research participants’ perception of the assurances and limitations of Certificates of Confidentiality.

Uses of data. This includes issues of obligation to publish, data sharing, and dissemination. How is research effectively disseminated? What should be emphasized or omitted? How are data used? Who is harmed or benefited? Should harmful data be suppressed or censored; what happens when it is? What are consequences of the various modes of dissemination? How can risks of data sharing be minimized and benefits maximized?

Example: O’Rourke et al. (2006) describe methods of preparing quantitative data for sharing so that its analytical value is optimized while minimizing the risk of disclosure of unique identities.

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Risk and Benefit

Risk, wrong, and harm. What might be considered in evaluating harm in research? How does one weigh moral wrongs (e.g., deception)? How is degree of risk assessed? How do various populations perceive risk? How can procedures be made safe? How is safety judged? How can researchers effectively communicate about risk to potential participants? These questions are usually context specific.

Example: Anderson and Iltes (2008) review the literature on physician-patient risk communication and summarize the results on ways to improve participants’ understanding of research risk.

Benefit, incentive, promise of social value. What benefits may arise from research? How may benefits be estimated and maximized? What kinds of collateral benefits can be offered to subjects or their communities? What are the effects of collateral benefits? What makes research socially useful? What makes research participation beneficial (or harmful) to the participants themselves and to the larger society? How do researchers’ ideas about what is beneficial differ from the views of subjects or their communities?

Example: It was long assumed that surveys and interviews of trauma victims would re-traumatize them. Newman, Risch, and Kassam-Adams (2006) review the trauma research literature and show that an objective and caring interviewer typically has the opposite effect and may even help the indi-
individual to gain useful perspective on his or her experience. DePrince and Chu (2008) further explore the conditions under which this occurs.

**Risk-benefit assessment.** How are the benefits of increased knowledge weighed against the risks of harm to individuals or groups or cost to society? How are these factors identified and weighed? How is risk justified? The methodology of decision theory in this area has rarely been applied to the examination of ethical issues in human research, but it is relevant.

Example: Lazovski, Losso, Krohmal, Emanuel, Grady, et al. (2009) survey persons in three countries who were participating in HIV clinical trials and find that many identified compelling benefits that were unrelated to the intervention and not considered by the researchers or IRBs.

### Other Influences on Research

**Research ethics committees.** How do they function? What are their effects on research participants, investigators, science, and society?

Example: Abbott and Grady (2010) review the empirical literature evaluating IRBs and report what is known and what remains to be learned.

**Other institutional influences.** The policies and practices of the larger institution in which research occurs set the tone and control the practices of researchers at least as much as the research ethics committee. What are the dynamics of these processes? What are effective methods for studying these sequestered processes and their effects on the ethical and scientific environment within the institution?

Example: DeVries, Anderson, and Martinson (2006) survey scientists at major research institutions and are regaled with stories of how arbitrary rules lead to researchers’ cutting corners and violating rules.

**Perceptions that influence research and ethical problem solving.** How do the perceptions of one another among the stakeholders in research influence scientific, ethical, and regulatory decisions?

Example: Lisa-Jo van den Scott (2012) describes the steps she must take to win the trust of Inuit communities, including her understanding of their beliefs and perceptions of the world.
Questionable, taboo, and controversial topics of research. Should research be done that might violate social norms, cause social harm, produce misleading findings, or be used in a politically harmful way? There are many perspectives on most such questions, and political correctness does not resolve these questions in the long run. What are the effects of studying such questions?

Example: Ditton and Lehane (2009) describe the complexities of doing research on persecuted immigrant populations who have escaped over the Thai border from Myanmar (Burma).

Scientific integrity and responsibility. What kinds of scientific misconduct may occur? What conditions surround misconduct? What conditions enable individual scientists to act with integrity and responsibility to prevent scientific misconduct?

Example: Martinson, Anderson, Crain, and DeVries (2006) survey researchers at major research institutions and find that their admissions of misconduct are related to their perception that the institution was not treating them fairly in various ways.

Ethics and politics. Charges of scientific irresponsibility or immorality may mask profound political differences. Issues of whom the investigator works for, who sponsors the research, and how the data are used raise ethical and political questions that are difficult to separate from one another. Case studies and analytic methods may provide useful insight into such questions.

Examples: Gardner and Lidz (2006) report that financial relationships between researchers and pharmaceutical firms are associated with less author contribution and more sponsor control over the research, raising concerns about bias in the design, conduct, and reporting of research. Slaughter, Feldman, and Thomas (2009) examine the institutional conflict of interest policies of major research universities and find most of them inadequate to manage conflict of interest adequately.

Human research literacy. The public and members of the news and entertainment media need information that builds understanding of and trust in clinical, biomedical, behavioral, and social research. How is the Internet being used to foster human research literacy (or misinformation)? What kinds of information are most useful? What kinds of research, or research issues, undercut public trust? What kinds of literacy and illiteracy have been fostered? What approaches to popularization are effective in building understanding and trust? What kinds of human research protection systems or mechanisms support public trust?

Example: Goodman, Dias, and Stafford (2010) describe a training program that increased research
literacy of community research workers to prepare them for collaborative work with academic researchers and empower them to utilize scientific methods to create social change in their communities.

*New technologies creating new methods.* Groundbreaking new discoveries and technologies in areas such as genetic research and fMRI imaging of brain activity have created new ways of studying human behavior and thinking. These also may reveal the most intimate details of ourselves, such as mistaken paternity and disease proneness. Not only are valid findings such as these very sensitive and possibly harmful, but worse, the interpretations of genomic and MRI data may also be in error. What precautions are needed with these technologies? As well, the Internet is offering many new ways to communicate and to do research.

Example: Illes and Racine (2008) review the ethical challenges that are emerging in advanced neuroimaging research in which researchers are tempted to speculate about things such as neural correlates of personality. Schaffer et al. (2009) have studied the way parents of critically ill children communicate about the pros and cons of enrolling their children in clinical trials.

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**Reflective Questions**

1. What research questions have you formulated that are of interest to you? How would such research help you to further your own (nonethics) research interests?
2. What methods would you favor using to embark on such research?
3. What examples did you find, if any, in this chapter that might guide you in undertaking such a project?
4. With whom might you collaborate in planning and conducting such research?
5. What difficulties, if any, do you perceive in undertaking such research?

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