

Manuscript Types Considered for Submission

Material appropriate for publication may be described with four cross-cutting categories: topics, fields or disciplines, approaches, and type of article.

Topics

These include the following topics:

Communication Issues: Recruitment; Informed consent; Deception; Relationships as a source of data; Community-based participatory research, community consultation and outreach; Language and meaning across cultures and contexts

- *Recruitment.* Research might involve various intermediaries (e.g., community gatekeepers, or in the case of “snowball sampling,” other subjects), and technologies (e.g., random-digit dialing). How do various approaches satisfy requirements of ethics and science?
- *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.
- *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.
- *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, participant, gatekeepers 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; how participants may be respected or wronged; what steps can be taken to de-identify participants; and ways to improve the accuracy of the observations and interpretations.
- *Community-based participatory research, Community consultation and outreach.* Before, during and after the research, investigators may become involved with subjects’ community to educate the researcher about what research approaches are acceptable to the community, to educate or thank subjects and their families, or to provide opportunities for mutual understanding. What are effective ways to fulfill these functions? What are the effects on validity, feasibility of future research at that site, the feelings of subjects and members of the community, and the way the findings are applied?
- *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?

Acquisition and Use of Data: Privacy; Confidentiality; Uses 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 best ways to understand and respect the privacy of research subjects.
(Note: *Privacy* is about persons and *Confidentiality* is about data.)
- **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?
- **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?

Risk and Benefit: Risk, wrong and harm; Benefit, incentive, promise of social value; Risk/benefit assessment

- **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? These questions are usually context specific.
- **Benefit and promise of research.** 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 community? 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?
- **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 examination of ethical issues in human research, but is relevant.

Theory, Method and Design: Validity; Modeling; Equitable treatment of participants; Technology, efficiency and sampling; Beliefs about knowledge

- **Beliefs about knowledge.** Beliefs about the nature of reality influence researchers' views on methodology and the products of research. When knowledge is considered intrinsically good, notions of censorship or limitation of research are unacceptable. However, when knowledge is considered as a form of power, the question of access to that power becomes an ethical issue. Similarly, when reality is considered something "out there" that can be studied objectively, methods such as deception seem more appropriate than when reality is regarded as a

construction composed of interaction between researcher and participant in which trust is important. A better understanding of stakeholders' beliefs about the nature of knowledge, and factors influencing these beliefs, is needed to inform understanding of how various stakeholders view science.

- *Validity*. For research to be ethical, it must be valid. However, other ethical considerations may impact validity, such as consent procedures that may muddle one's random sampling design. How are these dilemmas resolved so that research compromises neither the autonomy and well-being of subjects, nor validity? How can rigor and respect be jointly optimized?
- *Modeling*. Modeling may be employed to improve accuracy and sophistication of prediction and empirical tests of complex ideas, e.g., about health, financial status, or education. It may improve sampling strategies, enable investigators to impute missing data, design more appropriate research and better estimate the number of subjects needed. How can this sophisticated methodology be put to optimal use in the service of ethics?
- *Equitable treatment of participants*. Issues of distributive and procedural justice arise in the process of planning, conducting and applying research, and call for empirical research. Many questions arise concerning ethical treatment of participants, such as: When is it unethical to withhold information about the sponsorship of research from subjects? Who benefits from the research? How are participants selected? When is random assignment or use of placebos acceptable?
- *Technology, efficiency & sampling*. New technologies and combinations thereof may be used to recruit, contact or observe subjects. What happens when these are used? Is science improved? Are ethical criteria met?

Other Influences on Research: Research ethics committees; Other institutional influences; Perceptions that influence research; Taboo, questionable and controversial topics of research; Scientific integrity and responsibility; Ethics and politics; Government and agency regulations and policies; Human-research literacy; Education in the responsible conduct of research (RCR)

- *Research ethics committees*. How do they function? What are their effects on research participants, investigators, science and society?
- *Other institutional influences on the research process*. 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?
- *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?
- *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 effects of studying such questions?
- *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?
- *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.

- *Government and agency regulations and policies.* 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?
- *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. What kinds of information are most useful within each of these four areas of human research? 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 protections systems or mechanisms support public trust?

Fields or Disciplines

Research may employ methods of various disciplines within social or behavioral science, biomedicine, pharmacology, or medical device fields. The work may occur in academic, health-care, industrial or other settings. Please identify discipline(s), method(s), and setting(s) in the abstract and method section. Most research may apply to any scientific context of human research. If specific to one context, please indicate this in key words, title and abstract.

Approaches or Sources of Data

Empirical research on research ethics is new, or seems new, to most investigators. In some cases it is an appropriate version of pilot research the investigator would normally conduct but not otherwise publish. It is motivated in various ways and **often** occurs without funding. For example:

- An ethical problem may need to be solved to ensure participant cooperation.
- An investigator may introduce an ethics-related experimental condition, such as anonymity, and observe respondent behavior or attitude compared to the behavior of those in the control group.
- An investigator may follow up to learn how subjects perceived their research experience.
- A new research topic may require a new approach, e.g., AIDS intervention research required the development of community consultation.
- An investigator may work in an area relevant to research ethics, e.g., socialization of scientists, decision making, or privacy behavior.
- An investigator may be embroiled in an ethical problem, e.g. accused of betrayal of subjects. She may then conduct research to understand the causes and prevention of this perception.
- An investigator may be puzzled by an ethical/methodological problem, e.g., how to conduct controlled experiments on intact organizations, and make development of needed methodology part of his career.

- An investigator may choose a career in empirical research ethics.
- How do investigators undertake such research? Several approaches are currently found in the literature. More are likely to emerge:
- Pilot studies are built into a larger study.
- Post-study evaluation is conducted via debriefing or follow-up.
- Surrogate subject studies are conducted.
- Ethics-related experiments are nested within larger studies.
- Existing data are reanalyzed for an ethics-related purpose.
- Multi-site research is a vehicle for examination of ethical questions, e.g., effects of culture, recruitment, amount of compensation, or other demographic or experimental variables, on aspects of subject perception or behavior such as satisfaction, compliance, or candor.
- Stand-alone experiments, surveys, ethnography, methodological analysis are conducted.
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Types of Articles

Although categories of articles are not mutually exclusive, a submission should state whether it is intended primarily as an original empirical research, review, or theoretical and/or methodological paper. If theoretical and/or methodological, the paper should include empirical data or results to demonstrate its applicability to solving ethical problems. “Theory” is used here in its various senses. For example, a paper might present a model, method or paradigm for studying the meanings of privacy in a given culture based on Laufer and Wolfe’s* theory of privacy, or a theory of informed consent might be used to guide the methodology of cognitive interviewing in creating consent communication that participants understand, and so on.

Some quantitative articles become more useful if accompanied by a case study or methodological paper that expands upon or illustrates the ideas that emerge from the quantitative presentation. The decision to seek an appropriate accompanying paper is sometimes made jointly by the editor and an author whose quantitative paper has been accepted for publication in *JERHRE*.

*Laufer, R.S., & Wolfe, M. (1977). Privacy as a concept and a social issue: A multidimensional developmental theory. *Journal of Social Issues*, 33, 44-87.