

# Human Subjects Research and the Internet: *Ethical Dilemmas*

by Rebecca Armstrong

The Internet — *or the use of the Internet* — is seen by many as the new frontier in gathering data from and about people (i.e., “human subjects”). This cyberspace medium can facilitate research ranging from surveys to naturalistic observations. For example, the Internet provides a potentially unlimited subject pool for surveys; it may facilitate the pre-screening of study participants; investigators can observe behavior and collect data; and research conducted over the Internet can reduce the need for laboratory space and staff. However, the vast potential of the Internet to improve scholarship in a wide variety of fields is dampened by concerns about the quality of the data, participant privacy and confidentiality, legal ramifications and social norms.

As more investigators use the Internet for the recruitment of research participants, as well as data collection, it is worthwhile to revisit the basic ethical principles of *autonomy*, *beneficence*, and *justice* that are the underpinnings of all human subject research. The federally mandated Institutional Review Boards (IRBs) serve as the institutional mechanism by which these principles are upheld. This article is not intended to provide answers but rather to raise questions and issues that should be considered when engaging in Internet research.

## *Autonomy — is manifested as voluntary participation and informed consent (as a process and documentation)*

- The federal regulations require signed informed consent from every research participant unless a waiver of signature is granted by the IRB, or the research is exempt from federal oversight. The Office of Human Research Protection (OHRP), the governmental oversight agency for human subject protection, has deemed electronic signatures obtained over the Internet to be invalid even though electronic signatures are accepted for interstate commerce. Researchers currently getting electronic signatures do not meet the federal regulatory requirement. Thus, the investigator must, in most cases, receive an original or faxed signature from the research participant.
- Participants must be able to legally consent to participate in research, thus the research participant must qualify as an “adult” under state law. It is difficult to screen out minors from Internet research as the age of majority varies with each state. Although some investigators use Internet monitoring software (SafeSurf or RSACi ratings) to screen out minors, or use adult check systems, however, such products are not foolproof.
- Where participant consent is required, the investigator has the duty to ensure that the participants understand what they are consenting to participate in. Is a “click” of your mouse equivalent to having a survey returned by mail or someone

staying on a telephone line for an interview? How can you determine the understanding of your participants? Some investigators incorporate “quiz” type questions to determine a participant’s understanding of the situation.

- When participants encounter a paper survey, they can skip a question, yet complete and return the survey to the investigator. This serves to ensure that with each question the participant is responding voluntarily. Is this same opportunity available to the participant in an on-line survey, or must the participant answer every question?
- When does a participant in a chat group or chat room have a reasonable expectation of privacy? Some argue that the Internet operates as a public space, and liken observing conduct on the Internet to observing adults in a mall or public park, thus alleviating the need for informed consent at all. However, do social norms of Internet use provide the expectation of privacy? Is there a difference when an investigator is a member of a chat group as opposed to being in a chat room available to everyone?
- If an investigator is participating in a chat room as a participant-observer, is this any more or less acceptable than “just lurking”?
- What are the investigator’s obligations, if any, to protect the privacy of participants in chat rooms or chat groups?
- What if an investigator wants to monitor wireless communication—say in a classroom as educational research? Have the IP addresses of the laptops been registered? Are individual student responses identifiable? What can a PI do to facilitate anonymity? If a PI “locks” the consent form in their computer, what should they be required to do to ensure the confidentiality of those soft copies?
- Confidentiality in cyberspace means something different than locking consent forms in a cabinet. How does an investigator protect the privacy of study participants who respond using the Internet? Can the participant’s IP address enable him or her to be associated with a study?

*Beneficence — as a principle is manifested in the complementary statements of a) do no harm; and 2) maximize the possible benefits and minimize the potential harms. Internet research poses its own risks, such as:*

- There are new ways in which confidentiality may be breached.
- Reduced opportunities (as compared to face-to-face data collection) for risk management by the investigator when the question being asked triggers an adverse reaction in the participant.

- Intrusion (deliberate or otherwise) into the investigator's data.

Suggestions for protecting participant privacy and confidentiality, and the investigator's data are identified below.

*Some protection:*

- Use SSL encryption.
- Try to avoid personalized (identifiable) surveys.
- Ensure ownership of data: a) contractual destruction; b) minimal server backups.
- Web servers should use security best practices: a) firewall; b) security patches; c) strong passwords; and, d) minimal access.

*More protection:*

- Web server encrypts data as it is collected (only researcher can decrypt).
- Web logs destroyed regularly.

These measures are not guarantees of privacy or untainted data.

**Justice** — *as a principle is manifested by having as research participants those who will benefit from the research. How can investigators provide equitable access in Internet research?*

- Investigators—through research protocol design—should be diligent in soliciting representative populations for participation in Internet research or in using the Internet to identify potential subjects.
- Internet access, while it may appear to be ubiquitous and therefore bias-free, in reality is subject to a phenomenon commonly referred to as the “Digital Divide”. The Digital Divide is where certain groups of people continue to have low rates of usage and access to computers, and the Internet. Such limitations in some studies may impair the validity and reliability of the data and the conclusions drawn.

A variety of professional organizations and federal agencies are addressing the questions and dilemmas raised by Internet research. This article identifies a few topics with the intent of stimulating thoughtful discussions. Included below are additional resources on this important new frontier in human subject research.

1. *Ethical and Legal Aspects of Human Subjects Protection in Cyberspace* (1999), <http://www.aaas.org/spp/dspp/sfrl/projects/intres/main.htm>
2. *Internet Based Research Interventions: Risk Minimization Strategies* (2001), <http://www.nimh.nih.gov/research/cyberchart.pdf>
3. *World-Wide Web Survey Research: Benefits, Potential Problems, and Solutions*, Schmidt, W. C. (1997). “Behavior Research Methods, Instruments & Computers,” 29(2), 274-279.
4. *Association of Internet Researchers Ethics Working Group - 2001 Preliminary Report*, <http://aoir.org/reports/ethics> (author's note — very good document)
5. *American Psychological Association*, <http://www.apa.org/monitor/apr00/> (author's note — entire April 2000 journal devoted to the Internet). ♦

# True: Sound Ethics Does Produce Good Science

by Pamela Burroff-Murr

While regulations and codes may seem onerous, they actually lead to better scientific results, said Charles McCarthy, an internationally known ethicist, in a February 7 talk on campus.

“Good science is sensitive to the rights and well-being of the subjects involved in a research study,” McCarthy told an audience of researchers, students and staff about the relationship between sound ethics and good science. “If we were to back off ethical standards in science, public support for funding would dry up. And that concerns all investigators.”

McCarthy is co-director of regulatory compliance oversight and education at Virginia Commonwealth University. He has held numerous ethics-related positions with the Department of Health and Human Services and the National Institutes of Health. As director of the Office for Protection from Research Risks, he was responsible for implementing policies for the protection of human research subjects in the United States and 80 other nations.

“Today, there may be up to 10 million human research participants,” McCarthy said. He related the history of Institutional Review Boards (IRB) being created to review research protocols. To McCarthy, IRB members are the heroes of modern science and deserve recognition for their commitment to protect the rights and well being of fellow citizens.

McCarthy referred his listeners to the Belmont Report — a must-read for any investigator — written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Studies. The Belmont Report set guidelines that assist investigators as they design research protocols that protect human research subjects.

McCarthy credited public scrutiny and Congressional pressure for the evolution of many of the current policies protecting human and animal research subjects. He suggested that this heightened public awareness grew out of the outrage over experiments conducted on concentration camp prisoners during World War II.

“An examination of the experiments conducted in the Nazi concentration camps found the data so flawed that the studies offered little or no value to science,” McCarthy said. After the war, the Nuremberg Code became the foundation for future policies on the ethical treatment of human research subjects. McCarthy added, “Using sound ethical protocols in research actually assists investigators with their data collection adding greater value to their contributions to science.”

McCarthy discussed the unique contribution that United States research institutions make to society, suggesting that these research institutions also serve as models to the world for their adherence to the sound ethics that produce good science.

For more information on The Nuremberg Code and the Belmont report, visit: <http://www.irb.purdue.edu/regfound.shtml>. ♦