

## **Ethical Guidelines and Considerations**

Here is an overview of the concerns associated with research and human subjects. We hope to stimulate your thinking about this important topic.

Think about this:

### **Corporate Scandals**

The Enron, WorldCom, ImClone, and Adelphia companies sent shock waves throughout our economic fabric. Whether the corporate scandals were individually orchestrated or institutionally ignored, the public trust was shattered yet again.

### **Governmental Abuses**

The White House, the intelligence services, and Congress are locked into a war of blame associated with the tragic events of 9/11 and subsequent actions. Public trust is once again being challenged.

### **Personal Failures and State Secrets**

Martha Stewart, Janet Jackson, Michael Jackson, Jayson Blair, and Jack Kelly all have stirred a variety of emotions among fans and followers. Whether the failing in question is cheating, performing provocative behaviors, or lying, the public is again assailed with trust-breaking behaviors.

Trust is one of the critical components of research, and it appears to be in short supply. As researchers, we face increasing difficulties in convincing potential participants to trust us.

### **Background Review**

In 1946, the world learned of even more brutality and indifference to human life during a trial of those who had sworn "*primum non nocere* (first do no harm)." Numerous incidents of inhumane experiments and countless cases of euthanasia resulted in the conviction of 16 doctors. Seven were executed.

[The Nuremberg Code of 1947](#) established specific guidelines for the medical profession in conducting research. These included voluntary consent, a requirement that the results cannot be obtained in other ways, and a requirement that subjects can terminate their participation.

[The Helsinki Declaration of 1964](#) provided very clear guidelines for biomedical practitioners. It also stipulated that independent committees should review certain research efforts.

The [Belmont Report](#) was the seminal document in later efforts to establish legal obligations for biomedical and behavioral research. The report was in response to tasking by the National Research Act of 1974. The report provided the public and researchers with clear principles and guidelines about ethical behaviors with human subjects. The report also outlined the mechanics of informed consent.

The [American Psychological Association](#) established ethical standards in 1953. Since then, 10 revisions have occurred. The [current \(2010\) version](#) provides practitioners with guidelines covering most (some would argue too many) professional activities.

## Federal Law, State Law, Professional Organizations

[45 CFR 46](#), a result of the Belmont Report, provides very clear and definitive guidance for those performing research with human subjects.

The federal regulation addresses the mechanics and process of ethical research. It covers

- institutional review board (IRB) use, construction, and procedures
- informed consent form (ICF) construction and application
- special (protected) population considerations

The state of Maryland is one of a number of states that have enacted [laws to protect human subjects](#). Additionally, many professional organizations, like the APA and the [American Medical Association](#), have established ethical codes of conduct that are often more restrictive than federal and state laws.

Federal law is clear: If you conduct research associated with federal money or support, you must comply. If you conduct research that is within the scope of the department or agency but is not supported, then the effort must be scrutinized by an IRB.

Maryland state law is a bit clearer; if human subjects participate in the research, then compliance with the federal regulations (45 CFR 46) is mandatory.

## Ethical Challenges

- **The Tuskegee Syphilis Study (1932)**—399 African-American men infected with syphilis were denied medical treatment so researchers could document the natural history of the disease.
- **Milgram's Obedience to Authority Experiments (1961-1962)**—Stanley Milgram conducted research that resulted in a finding that 65 percent of the participants were willing to administer a shock that would deliver a potentially lethal electrical voltage to a "participant."
- **Zimbardo's Stanford Prison Experiment (1971)**—Philip Zimbardo conducted an experiment that created a situation that altered individuals' "normal" social behaviors in sadistic and torturous behaviors. The additional problem was that the researcher became so involved with the research that he was unable to see what was occurring until an outsider pointed it out.
- **Virginia Commonwealth University Research Program (2000)**—A concerned father inadvertently learned several questions on a survey in a research project that his daughter was participating in. One question asked if her father ever suffered from depression, which in and of itself wasn't overly objectionable. The second question was about whether the father had abnormal genitalia. After receiving inadequate responses to his requests for more information from both the researcher and the administration of VCU, he went to the FDA. VCU had to shut down 1,100 federally funded programs, costing around \$10 million, while each was reviewed to ensure compliance with federal law.
- **Johns Hopkins University/Kennedy Krieger [Lead Paint Experiment](#) (2001)**— the Maryland Court of Appeals overturned lower court findings. Researchers at the Kennedy Krieger Institute were monitoring lead levels in children in homes with known lead paint. This reversal placed JHU on the U.S. Department of Health and Human Service's radar screen for review.

- **PolyHeme Study (2004)**—PolyHeme was experimenting on the effectiveness of artificial blood. The experiment used victims of catastrophic events who would die without intervention without the participants' consent. The justification was that the individuals would die without this transfusion. By the way, VCU Hospital was trying to be one of the participating institutions.
- The Association of Internet Researchers has issued its preliminary report on the ethical conduct of research using the Internet. The APA recently published several articles on studies using the Internet. Whether we are using the Internet to conduct research or conducting research on users, we face newer questions associated with the "use" of human subjects.

### **Violations of the APA's Ethical Principles of Psychologists and Code of Conduct**

Every year, in compliance with federal law, nonprofit organizations are required to produce a report to members. Part of the APA's yearly report includes reporting information from the various internal committees and departments. The Ethics Office, within the Executive Office, provides a yearly notice that indicates those APA members who were either expelled or who resigned from the APA because of verified or possible violations of the APA's [Ethical Principles of Psychologists and Code of Conduct](#).