Ethical Considerations in Data Collection

Psychology (Statistics) 484

Statistics, Ethics, and the Social and Behavioral Sciences

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Beginning Quotations

My own view is that taping of conversations for historical purposes was a bad decision.
– Richard Nixon

To say a sheep has five legs doesn't make it so.
– Abraham Lincoln

When the president does it, that means it is not illegal.
– Richard Nixon

Provide only such expert testimony as you would be willing to have peer reviewed.
– American Statistical Association (*Ethical Guidelines for Statistical Practice*)

In God we trust; all others must bring data.
– W. Edwards Deming

Week 14: Ethical Considerations in Data Collection

— ethical considerations in data collection and analysis involving human experimentation; the Nazi Doctors' Trial and the Nuremberg Code; the Tuskegee syphilis study and the Belmont Report; the Declaration of Helsinki and the conduct of foreign clinical trials

Required Reading:
SGEP(421–447) —
The Nazi Doctors' Trial and the Nuremberg Code
The National Research Act of 1974
The Declaration of Helsinki

Popular Articles —
Whose Body is it, Anyway? Atul Gawande (*New Yorker*, October 4, 1999)
Drug Companies & Doctors: A Story of Corruption, Marcia Angell (*New York Review of Books*, January 15, 2009)

Suggested Reading:
Appendix: The Belmont Report

Film: *Miss Evers' Boys* (118 minutes)

Introduction

Statisticians and other quantitatively oriented behavioral and medical scientists who do analyses and interpretations of data obtained from human experimentation are expected to follow the established ethical guidelines that control such experimentation.

The American Statistical Association, for example, in its *Ethical Guidelines* (1999), has an explicit section entitled "Responsibilities to Research Subjects (including census or survey respondents and persons and organizations supplying data from administrative records, as well as subjects of physically or psychologically invasive research)."

We give four of the more germane points from this particular section (and reproduce the complete ASA Ethical Guidelines in an appendix in your required reading):

1. Know about and adhere to appropriate rules for the protection of human subjects, including particularly vulnerable or other special populations that may be subject to special risks or may not be fully able to protect their own interests. Ensure adequate planning to support the practical value of the research, validity of expected results, ability to provide the protection promised, and consideration of all other ethical issues involved.

6. Before participating in a study involving human beings or organizations, analyzing data from such a study, or accepting resulting manuscripts for review, consider whether appropriate research subject approvals were obtained. (This safeguard will lower your risk of learning only after the fact that you have collaborated on an unethical study.) Consider also what assurances of privacy and confidentiality were given and abide by those assurances.

7. Avoid or minimize the use of deception. Where it is necessary and provides significant knowledge—as in some psychological, sociological, and other research—ensure prior independent ethical review of the protocol and continued monitoring of the research.

8. Where full disclosure of study parameters to subjects or other investigators is not advisable, as in some randomized clinical trials, generally inform them of the nature of the information withheld and the reason for withholding it. As with deception, ensure independent ethical review of the protocol and continued monitoring of the research.

We will discuss three landmarks in the development of ethical guidelines for human experimentation:

the Nuremberg Code resulting from the war crimes trial of Nazi doctors after the close of World War II,

the passage of the National Research Act in 1974 partly because of public exposure of the Tuskegee syphilis experiment that ran from 1932 to 1972,

and the Declaration of Helsinki first adopted in 1964 by the World Medical Association (and revised many times since) that until recently has been the guiding document internationally for all medically related experimental trials of drugs, medical products, vaccines, and similar health-related interventions.

The Nazi Doctors' Trial and the Nuremberg Code

A momentous event in the ethics of human experimentation occurred with the Nazi Doctors' Trial in Nuremberg in 1946.

Formally known as *United States of America v. Karl Brandt et al.*, it produced The Nuremberg Code within the final ruling given by Justice Walter Beals.

This short statement of ten principles has formed the basis for all later codifications of ethical principles governing human experimentation.

The two United States doctors attached to the trial as advisers, Andrew Ivy and Leo Alexander, are believed jointly responsible for the wording of the Code in the form used by Justice Beals.

The ten short principles are reproduced in an appendix in your required reading, with the first rule of informed consent being the longest and most important and given below.

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him/her to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

As noted, all later incarnations of ethical guidelines for human experimentation include variations on these summary statements issued at Nuremberg, except for the fifth principle.

Here, it is argued that experimentation, unethical to begin with, doesn't somehow become ethical merely by having the experimental researchers or physicians also willing to take part.

Also, a study can be evaluated as being unethical at its outset, irrespective of the value of the data that might be obtained.

No matter how laudable the goal, it can't justify an unethical mechanism for reaching it.

Or, to put a Latin phrase to good use, this is not a situation of *exitus acta probat* (the outcome justifies the deed).

The person named in the Nuremberg Doctors' Trial, Karl Brandt, was Adolf Hitler's personal physician, and head of the administration for the Nazi euthanasia program from 1939 onward.

In his position as Major General Reich Commissioner for Health and Sanitation, he was involved in incredibly brutal human experimentation.

Brandt and six of the other named defendants were convicted of medical war crimes, many carried out at various Third Reich concentration camps, and were hanged at Landsberg Prison.

The attorney for Karl Brandt raised several points of defense suggesting there were no real differences between what the Nazi doctors had done and the type of human experimentation performed in the United States.

One major instance cited was the study of malaria vaccine on prisoners at Stateville Prison in Joliet, Illinois.

This story was prominently featured in *LIFE* magazine (June 4, 1945), under the title, "Prisoner Malaria: Convicts Expose Themselves to Disease So Doctors Can Study It."

A second defense argument raised by Brandt's attorney was that the view of undesirable races and the resulting population policies of the Third Reich were not unusual or even unique to Nazi Germany.

As documentation of this, excerpts from Madison Grant's, *The Passing of the Great Race* (1916), were introduced as evidence.

Supposedly, Grant's popular book was Adolf Hilter's favorite; he even wrote Grant a fan letter applauding it and commenting that the book was "his Bible."

We redact in an appendix in your required reading some of Grant's fourth chapter, *The Competition of Races*, with parts italicized that were used as explicit defense evidence for Brandt.

The National Research Act of 1974

The Tuskegee syphilis study is arguably the most infamous and unethical biomedical study ever performed in the United States.

It was conducted by the United States Public Health Service from 1932 until its exposure in the national press in 1972.

For some historical background, we redact below the introduction to the Wikipedia article on the "Tuskegee syphilis experiment".

In a White House ceremony on May 16, 1997 that was attended by five of the eight remaining study survivors, President Bill Clinton formally apologized for the Tuskegee study; this statement is in the endnotes of your required reading.

The Public Health Service, working with the Tuskegee Institute, began the study in 1932. Investigators enrolled in the study 399 impoverished African-American sharecroppers from Macon County, Alabama, infected with syphilis. For participating in the study, the men were given free medical exams, free meals and free burial insurance. They were never told they had syphilis, nor were they ever treated for it. According to the Centers for Disease Control, the men were told they were being treated for "bad blood," a local term used to describe several illnesses, including syphilis, anemia and fatigue.

The 40-year study was controversial for reasons related to ethical standards, primarily because researchers failed to treat patients appropriately after the 1940s validation of penicillin as an effective cure for the disease. Revelation of study failures led to major changes in United States law and regulation on the protection of participants in clinical studies. Now studies require informed consent (with exceptions possible for United States Federal agencies which can be kept secret by Executive Order), communication of diagnosis, and accurate reporting of test results.

By 1947 penicillin had become the standard treatment for syphilis. Choices might have included treating all syphilitic subjects and closing the study, or splitting off a control group for testing with penicillin. Instead, the Tuskegee scientists continued the study, withholding penicillin and information about it from the patients. In addition, scientists prevented participants from accessing syphilis treatment programs available to others in the area. The study continued, under numerous supervisors, until 1972, when a leak to the press resulted in its termination. Victims included numerous men who died of syphilis, wives who contracted the disease, and children born with congenital syphilis.

The *National Research Act* (of 1974) was passed partly because of the Tuskegee study.

It created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to oversee and regulate human experimentation.

In turn, this Act lead to the 1979 Belmont Report, named for the Smithsonian Institution's Belmont Conference Center.

The Report laid out the basic ethical principles identified by the Commission over some four years of deliberation.

It lead to the formation of the Office for Human Research Protection (OHRP) within the United States Department of Heath and Human Services, and to the establishment of the now ubiquitous Institutional Review Boards for the protection of human subjects in all forms of medical and behavioral experimentation.

The main body of the Belmont Report is given in an appendix to your required reading.

Explicit attention should be focused on the three general and controlling ethical principles: respect for persons, beneficence, and justice.

The Declaration of Helsinki

From the late 1970s and continuing to the present, the International Committee of Medical Journal Editors has regularly updated a set of guidelines for writing and editing in biomedical publication.

This document is entitled *Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications*.

It includes the following section on the Protection of Human Subjects and Animals in Research:

When reporting experiments on human subjects, authors should indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. When reporting experiments on animals, authors should indicate whether the institutional and national guide for the care and use of laboratory animals was followed.

As this paragraph indicates, the Declaration of Helsinki adopted by the World Medical Association is to be the controlling set of ethical guidelines for human (medical) experimentation.

The 2008 revision is given in an appendix to your required reading (with some parts italicized that are commented on in the reading).

As of October 27, 2008, the United States Food and Drug Administration (FDA) discontinued its reliance on the Declaration of Helsinki (DOH) in favor of an alternative—Guideline for Good Clinical Practice (GCP)—developed with significant input from the large international drug companies (see International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use).

Part of a short item that appeared in the *Lancet* (2009, *373*, 13–14) is given in your required reading ("Helsinki Discords: FDA, Ethics, and International Drug Trials"; Jonathan Kimmelman, Charles Weijer, and Eric Meslin).