

Data Ethics

The American Statistical Association is probably the largest and most well-known organization of statisticians in the world. Occasionally, we will look at articles in this class that were published in one of their many journals and other publications. On their website (www.amstat.org), this association makes its emphasis on ethics well known. Clicking on “Ethical Guidelines” leads to <http://www.amstat.org/about/ethicalguidelines.cfm> which outlines their “Ethical Guidelines for Statistical Practice”. A portion of these guidelines:

The **Ethical Guidelines** address eight general topic areas and specify important ethical considerations under each topic.

A. Professionalism points out the need for competence, judgment, diligence, self-respect, and worthiness of the respect of other people.

B. Responsibilities to Funders, Clients, and Employers discusses the practitioner's responsibility for assuring that statistical work is suitable to the needs and resources of those who are paying for it, that funders understand the capabilities and limitations of statistics in addressing their problem, and that the funder's confidential information is protected.

C. Responsibilities in Publications and Testimony addresses the need to report sufficient information to give readers, including other practitioners, a clear understanding of the intent of the work, how and by whom it was performed, and any limitations on its validity.

D. Responsibilities to Research Subjects describes requirements for protecting the interests of human and animal subjects of research—not only during data collection but also in the analysis, interpretation, and publication of the resulting findings.

E. Responsibilities to Research Team Colleagues addresses the mutual responsibilities of professionals participating in multidisciplinary research teams.

F. Responsibilities to Other Statisticians or Statistical Practitioners notes the interdependence of professionals doing similar work, whether in the same or different organizations. Basically, they must contribute to the strength of their professions overall by sharing nonproprietary data and methods, participating in peer review, and respecting differing professional opinions.

G. Responsibilities Regarding Allegations of Misconduct addresses the sometimes painful process of investigating potential ethical violations and treating those involved with both justice and respect.

H. Responsibilities of Employers, Including Organizations, Individuals, Attorneys, or Other Clients Employing Statistical Practitioners encourages employers and clients to recognize the highly interdependent nature of statistical ethics and statistical validity. Employers and clients must not pressure practitioners to produce a particular “result,” regardless of its statistical validity. They must avoid the potential social harm that can result from the dissemination of false or misleading statistical work.

These are a portion of the guidelines of the American Statistical Association, but you can imagine that statistical ethics is woven throughout many disciplines. We will think about ethics in statistics and related studies from two main directions: as the consumer of data and as the reporter of data.

Ethics Violation?

There are many obvious ethics violations which are hopefully obvious to the general public: using deception in order to obtain responses, publishing fake data, leaving subjects out of the analysis because their results don't say what you want them to say, etc... But other ethics violations are not so obvious and are the subject of debate. We need to have systems in place to define ethical violations and help avoid them.

Federal Guidelines to Protect Human Subjects in Research

Federal law requires any research that is directly or indirectly supported by the Department of Health and Human Services to have an **Institutional Review Board** which reviews all planned studies in advance *to protect the subjects from possible harm*. Facts: The IRB

- Does not decide whether the study will produce valuable information
- Must have at least five members
 - At least one scientist, one non-scientist, at least one unaffiliated with the organization
 - Members should be diverse (race, gender, and culture)

Check out our university's IRB <http://orc.research.sc.edu/irb.shtml>

Also, if the research involves human subjects, **Informed Consent** must be obtained before data are collected.

- Informed in advance about any risk of harm
- Consent is usually in writing

All individual data must be kept **confidential**.

- Only statistical summaries for groups of subjects may be made public
- **Anonymity** – subjects' names are not known, even to the director of the study
 - difficult to follow-up with the patient later
 - Anonymity is not common in statistical studies

A 72-yr old man with M.S. is hospitalized. His doc feels he may need to be placed on a feeding tube to ensure adequate nourishment. He asks the patient about this in the morning and the patient agrees. However, in the evening (before the tube has been placed), the patient becomes disoriented and seems confused about his decision to have the feeding tube placed. He tells the doc he doesn't want it in. The doc revisits the question in the morning, when the patient is again lucid. Unable to recall his state of mind from the previous evening, the patient again agrees to the procedure. Do you believe the patient has given informed consent to this procedure?

- A. Yes B. No

An IRB for a university approved to offer free HIV screening. A flyer says that for persons who come for testing, a code is used instead of your own name. You receive a copy of the report for your information, but only the code identifies the report as yours. You can learn the results of the test by coming in person to pick up the report, still w/o giving your name. This practice offers

- A. Anonymity B. Confidentiality C. Both anonymity and confidentiality

Recall: **Clinical trials** are experiments that study the effectiveness of medical treatments on actual patients. Clinical trials use randomized comparative experiments to study the effectiveness of newly proposed treatments / drugs, but can be risky.

World Medical Association

The World Medical Association was formed in 1947 and its mission is to “to serve humanity by endeavoring to achieve the highest international standards in Medical Education, Medical Science, Medical Art and Medical Ethics, and Health Care for all people in the world.” They developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. One of their statements is, “In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.”

Because the well-being of subjects must come first, medical treatments can be tested in clinical trials **ONLY** when there is reason to hope that they will help the patients who are the subjects in the trials. Future benefits alone are not enough to justify any experiment with human subjects.

Famous Unethical Study - Tuskegee Syphilis Study

In the 1930s syphilis was common among black men in the rural South. The Public Health Service recruited 399 poor black sharecroppers w/ syphilis and 201 others w/o the disease in order to observe how syphilis progressed when no treatment was given over the period from 1932 – 1972 – even after penicillin became a standard treatment in the 40’s. Word leaked out and forced an end to the study in 1972. This is one of the most infamous cases of biomedical research and was one main reason IRB’s were formed.

Are Placebo Controls Ethical?

Placebo controls have long been debated in terms of ethics. There are arguments for and against them. Let’s take a look at a recent placebo controlled experiment and discuss some ethical debates that may arise.

<http://www.nytimes.com/2010/09/19/health/research/19trial.html>