Human Subjects

Principles:

Respect

Justice

Beneficence

which generally requires

Informed consent

• Reasonable risk/benefit ratio

• Equitable selection of treatments

Statistical Ethics

Aaron Rendahl slides by Gary W. Oehlert, rev. by S. Weisberg

> School of Statistics University of Minnesota

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Human (and Animal) Subjects, continued

Research design must

- Balance benefits against harm
- Use efficient, correctly sized designs
- Maximize information extracted from subjects
- Consider interim analysis
- Avoid placebo-controlled testing when the condition is harmful
- Respect privacy (HIPPA: It's the law!)

Institutional Review Board

Federal funds & human subjects → IRB

IRB protects rights and welfare of human subjects.

IRB must approve any project with human subjects.

Non-profits (e.g., Universities) generally have their own volunteer IRBs; other research orgs may use professional IRBs.

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Investigator must

- Possess skills needed for the research.
- Design research that meets risk/beneift criteria
- Submit research plans to IRB
- Ensure prior informed consent
- Protect vulnerable populations
- Train personnel
- Adhere to high ethical standards
- Ensure privacy
- Keep records/make reports
- Comply with all regulations

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IRB will

but...

Weigh risks and benefits

Deny substandard designs

Researchers don't like IRB's.

• IRB's can be very slow

• IRB's can ask for the impossible.

• Provide oversight through completion

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Social Responsibility

As a scientist

- To keep an open mind. Report honestly what you see.
- To seek evidence and not accept things at face value.
- To exercise due diligence and not be sloppy.
- To make full disclosure to the extent possible.
- To stay within the limits of your expertise.
- Don't over interpret.

Social Responsibility

As a member of society

- To use resources wisely.
- To credit sources and acknowledge priority.
- To deal fairly with colleagues and subordinates.
- To act on ethical breaches by others.

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Ethics for statisticians

Finally, we now look at some ethical ideas that target statistics a little more closely.

Sometimes statistics is science, so we need scientific ethics.

Sometimes statistics is a business, so we need business ethics

Sometimes statistics is societal, so we need social ethics.

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Professionalism

- Guard against predisposition of results
- Weep current in methodology
- Acquire adequate statistical and subject matter expertise
- Work with ethical collaborators
- Sample Assure appropriateness of procedures (even automated ones)
- O Deal with multiple comparisons
- Respect contributions and IP of others
- Disclose conflicts of interest

ASA Guidelines

www.amstat.org/profession/index.cfm?fuseaction=ethicalstatistics These guidelines list eight areas to consider.

We begin with the American Statistical Association's Ethical Guidelines for

Funders, Clients, Employers

Statistical Practice, which can be found at

- When possible, present a choice among valid alternatives
- Clearly state your qualifications and experience
- Clarify roles in a project
- On't work towards predetermined outcome
- Fulfill commitments
- Accept responsibility for your performance

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Publication and Testimony

- Maintain personal responsibility for work bearing your name
- Report assumptions and question them
- Make it clear who did statistical work (pubs or testimony)
- 4 Have clear basis for authorship order
- Account for all data considered
- Report sources and adequacy of data
- Report/document data cleaning/imputation procedures
- Address potential confounding variables
- Identify financial sponsor
- Report limits on inference and sources of error
- Share data (modulo privacy/confidentiality)
- Promptly and publicly correct errors
- Write to the audience

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Official Statistics

- "... unaddressed ethical issues simply threaten the credibility of a statistical agency, undermining the trust that data providers, the public, and policy makers place in the agency or government statistical work generally."
- Use sound methodology.
- Privacy vs collective needs (homeland security, for example)
- Conflict between politics and science
- Equal and public access to data
- Work to maintain the integrity of statistical agencies and national statistical offices. Without good data, can we expect good decisions?
- "Biometrics".

Source: W. Seltzer (2005). Official statistics and statistical ethics: Selected Issues. ISI proceedings.

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Misconduct

- On not condone careless, incompetent, or unethical statistical practices
- Deplore professional misconduct
- Oifferences of opinion and honest error are not misconduct
- Follow procedures in a misconduct investigation
- 6 Help pick up pieces after misconduct investigation
- O not retaliate against whistle blowers

Statistics and the Law

Is there objective, legal truth?

Ref: P. Meier (1986), "Damned Liars and Expert Witnesses," JASA, 81, 269-276.

Sales tax has been erroneously applied to items not subject to tax. Plaintiff seeks to estimate the amount of the tax applied. Available are sales slips for 826 business days; all sales slips must be examined by hand to determine amount, a very expensive proposition.

As statistician for the *plaintiff*, what do you do?

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If you work for the defense

Suppose sampling had been done imperfectly by the other side, for example, using some systematic method. What is your role?

- ...if you believe sampling was not representative?
- ... if you believe that the bias caused by poor sampling is minor?
- ... if the sampling for the other side was done by "Dr. Deming or Professor Cochran"?

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It's the law

SD rule "... as a general rule ... if the difference between the expected value and the observed number is greater than 2 or 3 standard deviations, then the hypothesis that the jury drawing [the issue in this case] was random would be suspect to a social scientist" Casteneda v. Partida

Preponderance of the evidence In a civil non-criminal lawsuit, decisions are based on the more convincing evidence and its probable truth or accuracy, and not on the amount of evidence. This contrasts with "beyond a reasonable doubt" in criminal trials. Thus, for example, a Bayes factor of 1.01 could be enough. Source: dictionary.law.com

From Meier, p. 270

"... Cochran was fond of telling of the occasion when he was called on to carry out a sampling study of ... retail stores, and he instructed that the sample consist of every tenth establishment ... in the Yellow Pages. The judge, he said, welcomed his expert testimony as a learning experience and remarked, after Cochran has been swarn, 'I am glad to head and learn from Professor Cochran about this scientific sampling business, because I know virtually nothing about it. In fact, about the only thing I do know is that you should not just start at the beginning and take every 10th after that."

Moral: Be overly cautious.

Corrupting influences, also from Meier

- If you find the expert you choose is independent and not firmly committed to your theory of the case, be cautious about putting him on the stand. Your cannot be sure of his answers on cross-examination. when I put an expert on the stand, he is going to know which side we are on." (John C. Sheperd, cited in Meier, p. 273)
- (T) he statistician is temped to give the definitive rather than a qualified answer to key questions ... [and] to ignore or minimize qualifications that he might emphasize in a more academic setting..." (Meier, p. 273)
- Bribery
- Flattery
- Oco-option to agree with the cause.
- Gladiatorial role.
- Personal views.

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