

Research Ethics

STAT8801 Statistical Consulting

School of Statistics
University of Minnesota

April 5, 2010

Minnesota Requirements

The University wants you to learn about

- 1 Authorship
- 2 Plagiarism
- 3 Peer review
- 4 Intellectual property
- 5 Conflict of interest
- 6 Fiscal management
- 7 Data management
- 8 Animal/human subjects
- 9 Social responsibility

More on requirements

Some of these are clearly ethics; others more like policy or etiquette.

Still, you need to know this in a research environment.

Refer to www.research.umn.edu/ethics for much more information and links to University policies.

Material from this lecture comes from there, often verbatim.

Authorship



It's publish or perish baby, and you have to get your name on articles to survive.

This can lead to all kinds of hijinx.

"Surely you were aware when you accepted the position, Professor, that it was publish or perish."

Authorship issues

- Who qualifies as an author?
- Who is responsible for content of paper?
- Order of authorship?
- How are other contributions acknowledged?
- Least publishable unit? (One big paper or many small ones)

Who qualifies as an author?

Different journals or fields may have specific guidelines. Generally

- 1 All authors must make a significant contribution to research, such as
 - ▶ Conceptualization and design
 - ▶ Collection of data
 - ▶ Analysis and/or interpretation of results
- 2 All authors must contribute to drafting and/or revising important parts of the manuscript
- 3 All authors must have final approval of the manuscript and accept responsibility for its integrity

Everyone who does 1,2,3 should be an author, and all authors should do 1,2,3, but not all authors are created equal.

Order of authorship

Order of authorship is generally

- Alphabetical, or
- Meaningful

When meaningful, first author is the main author, e.g., has major ideas, collects most data, proves more theorems, writes first draft.

First author is the big cheese.

First authorship is a big deal.

First and/or senior author

In statistics, senior author is often a mentor.

In lab sciences, senior author usually overall investigator in charge of lab.

Senior author may or may not be first author.

When not first, senior is usually last.

First and senior authors decide who else is author, and in what order.

Ideally, authorship and order decided before writing (or even research) begins.

Coauthorship of papers can be appropriate when the consultant in the Service provides significant input to a final research product.

Recognition of the work of the Consulting Service is always appropriate. You could add a statement similar to the following to your publications: “The Statistical Consulting Service at the University of Minnesota and in particular [name the consultant] helped with the design and analysis of this experiment [or study or project].”

Articles Please send copies of all articles that recognize the Statistical Consulting Service to clinic@stat.umn.edu, or by regular mail to Sanford Weisberg, School of Statistics, 312 Ford Hall, Minneapolis Campus.

Many forms:

- Word for word copying without quotation or citation.
- Stitching together random bits from various sources without careful identification.
- Paraphrase without acknowledgment of the original.
- Casual repetition of great term or phrase.

Martin, Ohrman, Wheatley.

How about this?

You have been chosen to referee a new submission to Very Important Journal written by well regarded Professor Knowitall.

You are a diligent reviewer, and look at Professor Knowitall's earlier paper in The Journal of Lesser Quality, and you find passages in the new paper of several paragraphs in length that are identical to the submitted paper.

Has Professor Knowitall done anything wrong? What should you do?

Plagiarism everywhere?

Many examples in science, academia, and journalism.

Very easy to do in a click-and-drag internet age.

However, only about 20 cases a year get reported to NSF and NIH.

“A Columbia University professor who was found to have committed numerous acts of plagiarism struck back at her accusers on Thursday, saying it was they who stole her work and accusing administrators of blackmail and intimidation.”

The professor was found guilty of appropriating ideas and even text from work of students in her department. The professor published before the students' work was published. The professor claims that students stole her work, although the findings of a hearing were that she stole from her students.

<http://chronicle.com/article/Columbia-U-Professor-Says-Her/536>

Manuscripts don't get published until accepted by editors.

Editors don't accept until advised by associate editors.

Associate editors don't advise until advised in turn by peer reviewers.

Similarly, granting agencies don't give money until advised by peer reviewers.

- Don't review when you're not an expert.
- Don't review when you're involved in a dispute.
- Review quickly.
- Keep all materials and correspondence confidential.
- Do not appropriate ideas/work from a manuscript or grant that you are reviewing.

Should article review be blind?

Intellectual Property: What is it?

Any invention, discovery, improvement, copyrightable work, integrated circuit mask work, trademark, trade secret, and licensable know-how and related rights. Intellectual property includes but is not limited to, individual or multimedia works of art or music, records of confidential information generated or maintained by the University, data texts, instructional materials, tests, bibliographies, research findings, organisms, cells, viruses, DNA sequences, other biological materials, probes, crystallographic coordinates, plant lines, chemical compounds, and theses. . . .

Intellectual Property a la Minnesota

. . . Intellectual property may exist in a written or electronic form, may be raw or derived, and may be in the form of text, multimedia, computer programs, spreadsheets, formatted fields in records or forms within files, databases, graphics, digital images, video and audio recordings, live video or audio broadcasts, performances, two or three-dimensional works of art, musical compositions, executions of processes, film, film strips, slides, charts, transparencies, other visual aid/aural aids or CD-ROMS.

University of Minnesota Intellectual Property Policy

Types of IP

- Copyright** A copyright protects the tangible expression of an idea, not the idea itself (e.g., a book, a research article, or a videotape).
- Patent** A patent protects the idea and gives the creator the right to exclude others from using the idea. To receive a patent, the creator must disclose in detail how to make his invention work and its use.
- Trademark** A trademark identifies and distinguishes an idea, written words, pictures, or products from those of competitors (e.g., golden arches).
- Trade Secret** A trade secret refers to information that is not publicly known, that produces economic benefit to the owner, and that the owner maintains as secret.

U of M Copyright Policy, 12/14/2007

In most cases, copyright belongs to the creator:

“The University’s mission articulates a commitment to sharing knowledge through education for a diverse community and application of that knowledge to benefit the people of the state, the nation, and the world. In this spirit, the University encourages faculty and students to exercise their interests in ownership and use of their copyrighted works in a manner that ensures the greatest possible scholarly and public access to their work. . . .

“Consistent with academic tradition, University faculty and students shall own the copyrights in the academic works they create, except for academic works described below . . . , or unless otherwise provided in a written agreement between the creator(s) and the University.”

<http://www1.umn.edu/regents/policies/academic/Copyright.pdf>
www.lib.umn.edu/copyright

Who owns what?

- 1 Professor KnowItAll presents oral lectures, and Student Writesitup copies them down. Student is the owner.
- 2 Professor KnowItAll reads his lectures, and Student Writesitup copies them down. KnowItAll is the owner.
- 3 Student writes a paper in a class. Student is the owner.
- 4 Student participates in a class blog. Who owns the student's remarks in the blog? Student is the owner.
- 5 Student's review of an article is posted on a class website. The following year, this post is required reading in a course at a different university. Is this a violation of copyright? Yes, but academic fair-use is a good defense (Senate Res. Comm minutes, 9/17/07)

Patent policy

Who owns the right to commercialize patents, sometimes called technology transfer, created from the intellectual work of employees?

- 1 Student course work. Always belongs to the student.
- 2 Research that can potentially produce income. University policy splits income between the investigators, the sponsoring department and the University. The split is very contentious.
- 3 Research sponsored by outside, non-governmental agencies. If there are prior agreements, then the agreement governs.

Other employment

Many employment contracts, including consulting, contain IP ownership clauses.

Read and check the terms of employment carefully!

If you are a SAS programmer for a drug company and you write the next great statistics package at home in your spare time, the drug company may still own it.

Do not try to sell what legally belongs to your employer!

Disclose IP to its owner.

Conflict of interest

A conflict of interest occurs when Academic Employee compromises his/her professional judgment in carrying out University teaching, research, outreach, or public service activities because of an external relationship that directly or indirectly affects the Financial Interest of the Academic Employee, and Family Member, or any Associated Entity.

Examples

- A major interest in a private firm by a faculty member who also has the decision-making responsibility in awarding a contract to that firm.
- Sponsorship of research by commercial firms in which the faculty member has a significant interest.
- Nepotism.

More Conflicts

- Scientific** Participation in review/referee panels regarding the allocation of resources or the publication of papers. Usually handled by excusing the person with the potential conflict.
- Academic** Utilization of the name and/or the resources of the University for personal gain.
- Commitment** Spending too much time on non-University activities (consulting, service, etc.) leading to a significant decrease in the time and effort devoted to the employer.

What to do?

Disclosure, Disclosure, Disclosure.

All potential conflicts must be disclosed to appropriate parties (e.g., supervisors).

There may be no problem, but make sure in advance.

Data management

Data take many forms:

- measurements
- images
- interviews
- recorded behaviors
- medical records
- school records
- physical artifacts
- etc.

- Reliability
 - ▶ Records should indicate what, why, who, when.
- Maintenance
 - ▶ Records should be permanent and err on the side of thoroughness.
- Retention
 - ▶ PI in charge of keeping data
 - ▶ But ...
- Access
 - ▶ Protect private records
 - ▶ Satisfy contractual requirements
 - ▶ May be subject to litigation

According to Wikipedia:

A clinical trial is a comparison test of a medication or other medical treatment (such as a medical device), versus a placebo (inactive look-a-like), other medications or devices, or the standard medical treatment for a patient's condition.

Clinical trials have endless possibility for ethical problems.

Classification of Clinical Trials (from Wikipedia)

Phase 0 trials to determine if drug/therapy is active in humans.

Phase I use small groups of healthy subjects to test for safety.

Phase II establish safety, dosage, and potential effectiveness.

Phase III Larger comparative trials. Allocation of patients, number of patients, and stopping rules are important statistical issues.
Leads to government approval

Phase IV Post-marketing surveillance.

Guinea Pigging

"Most drug studies used to take place in medical schools and teaching hospitals. Pharmaceutical companies developed the drugs, but they contracted with academic physicians to carry out the clinical testing. According to The New England Journal of Medicine, as recently as 1991 eighty per cent of industry-sponsored trials were conducted in academic health centers. . . Impatient with the slow pace of academic bureaucracies, pharmaceutical companies have moved trials to the private sector, where more than seventy per cent of them are now conducted."

Carl Elliot, "Guinea-pigging; Healthy human subjects for drug-safety trials are in demand. But is it a living?," The New Yorker, January 7, 2008

Human Subjects

Principles:

- Respect
- Beneficence
- Justice

which generally requires

- Informed consent
- Reasonable risk/benefit ratio
- Equitable selection of treatments

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.

Investigator must

- Possess skills needed for the research
- Design research that meets risk/benefit 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

IRB will

- Weigh risks and benefits
- Deny substandard designs
- Provide oversight through completion

but. . .

- Researchers don't like IRB's.
- IRB's can ask for the impossible.
- IRB's can be very slow

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.