Responsible Conduct of Research

Francis L. Macrina
Vice President for Research
Virginia Commonwealth University

VCU

Science in the public eye

How science works

Lessons from Reading the Headlines….

1986 "Oat Bran may be the Next Miracle Food"

1988 "But not by Oats Alone"

1989 "Hot on the Heels of Oat Bran"

1990 "Oat Bran's Claims Weakened"

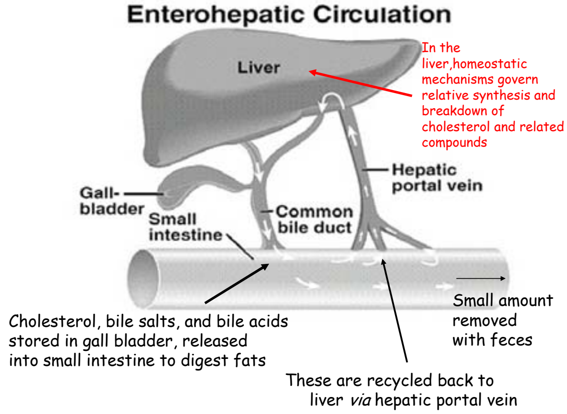
1990 "Oat Bran Bites the Dust"

1991 "New Oat Bran Study Says Cholesterol is Lowered"

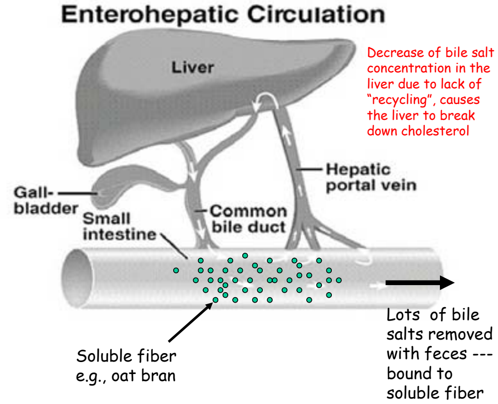
1992 "Oat Bran Really Does Cut Cholesterol"

1992 "Lots of Oat Bran Found to Cut Cholesterol"

Enterohepatic Circulation



Enterohepatic Circulation



The Textbook Scientific Method

1. Create a hypothesis
2. Test the hypothesis
3. Hypothesis not supported: modify it or return to step 1
4. Hypothesis supported: devise new tests to prove it wrong
5. Hypothesis not proven wrong: accept, publish, and build on it
6. Well tested hypotheses that withstand experimental scrutiny become part of the body of scientific knowledge

In reality…

•The scientific method is an ideal that may confuse the public

•It is not designed to prove, but to disprove

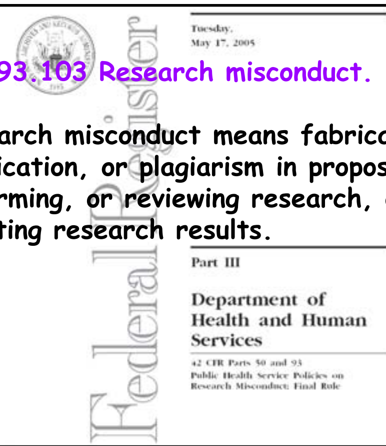
•It depends on facts and observations that are subject to current technology

•It necessitates reinterpretation

Recent Timeline Considering Scientific Conduct

Mid 1970-1980s	Highly publicized cases of alleged scientific misconduct grow in number
Early 1980s	Congressional hearings on fraud in biomedical research
Late 1980s-1990s	Infrastructure: definitions and policies; NIH mandated education
1999-2001	Incidents and investigations: human subject experimentation; more mandated education
2001→	Revised definitions and broad based emerging educational policies
2005	Revised Federal Regulations on Research Misconduct
2006	High profile cases continue in the media
2007	NSF mandated education

Sec. 93.103 Research misconduct.



Research misconduct means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

(a) Fabrication is making up data or results and recording or reporting them.

(b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

(c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

(d) Research misconduct does not include honest error or differences of opinion.

Prime Time Live

The reporting of science in the media.

Handling of allegations of misconduct by:
- the government
- the scientific infrastructure

The behavior of scientists.

Insights on how science works.

Lessons learned?

April 8, 1992
ABC's Prime Time Live

Shown with permission

Many lessons can be drawn from this early intense period and most suggest that science requires greater modesty.

N.Eng. J. Med. 12/11/03

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Cancer Institute

Memorandum

Date: August 19, 1985

From: Chief, Laboratory of Tumor Cell Biology, DTP, DCT, NCI

Subject: Science Article May 1983

To: Associate Director, NCI

"Over the course of this work we were responding to a public health crisis and the need to develop useful assays such as the ELISA screening assay. We did not intend to keep records of legal standing and they are often incomplete. In contrast to this rather normal behavior is the meticulous and apparently premeditated documentation of others interested , it seems, more in patents and notoriety."

"the poor quality and scant extent of his laboratory records was striking"

"…those notes which did exist were overwhelmingly cryptic and obscure, lacking even minimal detail necessary to understand what was done, what methods were used, and what results were obtained."

OSI Investigation
Crewdson, p. 417

When I came there was no such thing as how you kept your notebook. In fact, nobody ever asked me if I kept a notebook. Later you could get investigated for not having the right notebook.

"Is there life after NIH?"
Gallo speech in Baltimore, MD
(Crewdson, p. 539)

Record Keeping and Data Management

Proper Record Keeping Yields

Authenticity: research records that are original, accurate and trust worthy

Accountability: fulfills an explicit or implicit obligation to keep appropriate records for sponsored research

Practical Applications: records allow people to reproduce and build on results

a properly kept data book is a teaching tool that may be used to demonstrate the process of analysis of results, hypothesis construction, and trouble shooting experiments to solve problems or corrects errors

properly kept records are critical to assigning credit, establishing priority, and, acquiring and defending intellectual property protection (e.g., patent protection)

Record Keeping and Scientific Misconduct

Some have argued that proper record keeping reduces the risk of scientific misconduct.

Investigation and prosecution of scientific misconduct allegations puts a burden on the resources of the scientific infrastructure. This burden is increased by incomplete or shoddy records.

Defending against research misconduct allegations is more difficult without good research records.

Keeping Useful Scientific Records

Useful databooks explain:

Why you did it

How you did it

Where materials are

What happened (and what didn't happen)

Your interpretation

What's next

Good databooks:

Are legible

Are well organized

Allow repetition of your experiments

Are the ultimate record of your scientific contributions

What do scientists recognize as data?

Quantitative data: graphs, recorded numbers, instrument output of any type, including photographic materials from which measurements can be made

Qualitative data: notes of any type (in any form), some types of instrument output, including photographic media

Original samples in unanalyzed form; e.g., biological specimens

Research tools: protocols in any form; computer software

Tools and Techniques

Preferred choice: bound notebook with consecutively numbered pages; sewn binding, with high quality, acid-free paper.

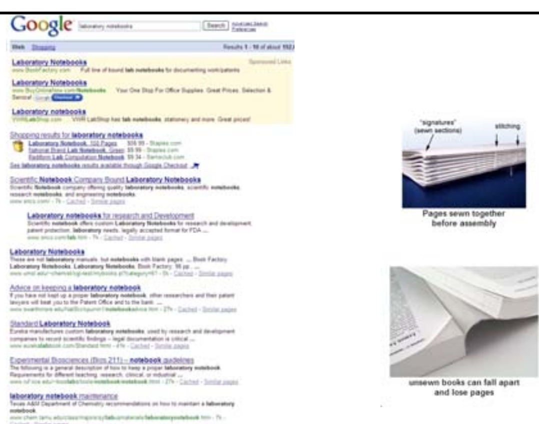
Write with a black ink; standard grade ball point pen is acceptable; do not use pencil or any pen with water soluble ink

Electronic Lab notebook:

The FDA has published standards: http://www.fda.gov/ora/compliance%5Fref/part11

Compliance is expensive: server based systems, encryption, electronic signatures

The challenge of affirming the originality of digital data:
When in doubt make paper copies, sign and date them



Corroboration:

Know when to have your data entries witnessed and dated by an impartial party who understands the work.

For applied research, records must demonstrate that the work was diligently pursued from conception to practice; there must be no evidence of abandonment in the research record

Handling of data books:

Keep books in safe place to prevent damage and destruction

Keep books secure to prevent their theft

Writing the Laboratory Notebook

Write legibly and in the first person with an eye towards sharing your notebook with your mentor and your colleagues.

Be organized: reserve opening pages for a Table of Contents; cross reference experiments wherever needed

Plan the use of your data book in the experiment
- -its placement and access is critical to your successful data recording
- -plan the time you will need for recording data and writing interpretations
- -write everything directly in the databook
- -never record data on the "first available piece of paper" and then transcript to the data book

Writing the Laboratory Notebook

Every experiment should have a
- -title, and all entry records should be dated
- -list of other investigators who are involved besides yourself
- -statement of purpose, a hypothesis, or a goal(s)
- -careful compilation of materials and equipment used including specific information about these resources (lot numbers, suppliers, equipment model/serial numbers

Record everything in detail: conception, process, data, interpretation, plans

Writing the Laboratory Notebook

Explain abbreviations and special terms

Record relevant discussions with mentor and lab colleagues (e.g., lab meetings)

Entries in the data book should be "stand alone" in terms of style: use headers, legends and annotations wherever needed

Never obliterate any entry in the data book. Cross out so that the information is still readable, annotate your reason, then date and initial the transaction.

Never remove a page from the data book

Writing the Laboratory Notebook

Mark through unused portions of pages with an X

Attached primary data in the data book (printouts, negatives, photos, etc.)

Data that cannot be practically affixed in the data book should be keyed, stored in a permanent, safe, and secure location in the lab suite; it should referenced accordingly in the data book

If appropriate maintain a methodology notebook; typically done at the lab group level than on an individual basis.

Laboratories should have a notebook tracking system

Ownership of Data and Data Books

Universities own data and data books based on interpretation of federal agency policy (e.g., NIH) and prevailing practice in higher education

Copies of data books may be made for practical reasons like back-up, using data to prepare reports and papers off-site, but only with the permission of the principal investigator or lab chief.

When you leave the lab for your next position, the lab books stay

Federal agencies typically require research records be kept for three years from the date of the filing of the final expenditure report. State law usually prevails of federal law, so if the state requirement for retention is more than 3 years that time would have to be honored (e.g., 5 years in Virginia).

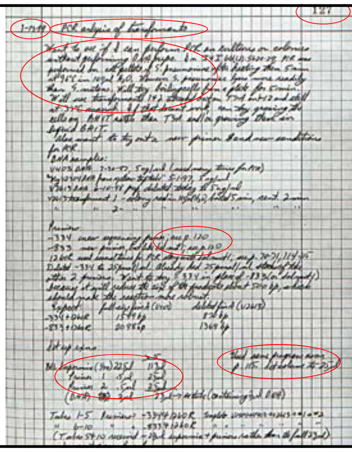
In the end, it's up to you!

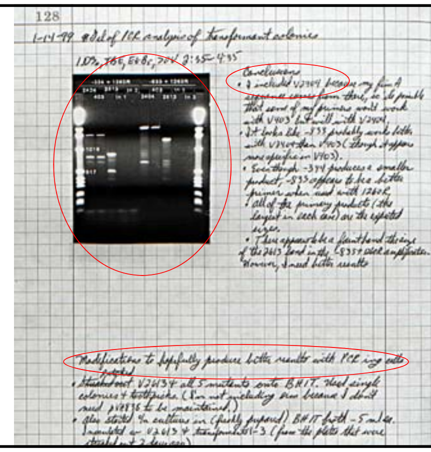
With few or any exceptions, funding agencies do not promote or enforce record keeping practices in a formal way

Two exceptions:

Some contractual research with for-profit sponsors

Research that may produce results with regulatory implications; in this case recordkeeping is in keeping with Good Laboratory Practices (GLP) as published by the US Food and Drug Administration.





University of Florida
http://rgp.ufl.edu/otl/goodrecords.html

DATA MANAGEMENT: RESEARCH RECORDS in NEW INVESTIGATORS: A QUICK GUIDE TO STARTING YOUR RESEARCH AT UCSF
http://www.research.ucsf.edu/QG/orQgDm.asp

Making the Right Moves: A Practical Guide to Scientific Management for Post Docs and New Faculty, Chapter 8: Data Management and Laboratory Notebooks, Burroughs Wellcome Fund and the Howard Hughes Medical Institutes.
http://www.medschool.vcu.edu/gp/HHMIMakingtheRightMoves2ndEd.html

NCSU Policy on Lab Notebook Maintenance
http://www.ncsu.edu/sparcs/compliance/integrity/lab_notebooks_supplement.doc

Fish and Richardson, P.C.
http://www.fr.com/practice/pdf/LABBOOK2.pdf

Dr. Brown's research group recently published an important paper in a leading physiology journal. Four months after the publication of the manuscript, Dr. Brown is contacted by a European colleague who has been unable to reproduce the results presented in two figures of the paper. Dr. Brown faxes copies of the pertinent laboratory protocols and recipes to his colleague and thinks no more of the discrepancy. Two months later, a graduate student in a competitor's laboratory contacts Dr. Brown and reports that he, too, was unable to reproduce the results. After this second call, Dr. Brown meets with Adam Green, the postdoctoral fellow who did the experiments in question. He asks Adam to bring his data book to the meeting so they can review the results together. Once in Dr. Brown's office, Adam confesses that he has been remiss in keeping his data book. He says that all of his electrophysiology experiments were recorded on VHS tapes with a live microphone into which he reported the experimental proceedings and observations. Adam transcribed these observations into his data book. However, there was a period of several days when his microphone was not working properly. Although Adam replaced the microphone as soon as he found that it was not working, he relied on his memory to transcribe the results of those particular experiments. After completing the figures for the manuscript, Adam was pleased to find that his data supported Dr. Brown's hypothesis. Dr. Brown comes to you for advice on how to handle this situation. What do you suggest?

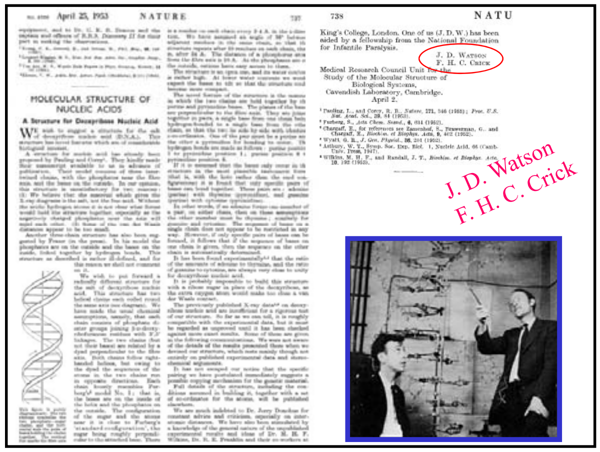
From *Scientific Integrity (3rd Ed.) by F. Macrina. Used with permission of ASM Press*

Core Curriculum in Responsible Conduct of Research

1. Record keeping and data management
2. Research Misconduct
3. Human subjects
4. Animal subjects
5. Collaboration in Science
6. Mentoring
7. Peer Review
8. Publication & Authorship
9. Conflicts of interest

http://www.courses.vcu.edu/rcr/

Authorship



Club Rules of Authorship

- A paradigm derived from the biomedical and natural sciences
- Research your discipline's sources to refine and extend the model

Club Rules of Authorship

- Publishers: Instructions to Authors
- Societies and Organizations: Guidelines for Authorship
- Institutions: Guidelines for Responsible Conduct

Instructions to Authors

1. *Archives of Oral Biology*
2. *Cell*
3. *Genetics*
4. *Journal of Bacteriology*
5. *Journal of Biological Chemistry*
6. *Journal of Dental Research*
7. *Journal of Experimental Medicine*
8. *Journal of Molecular Biology*
9. *Nature*
10. *New England Journal of Medicine*
11. *Proceedings of the National Academy (USA)*
12. *Science*

Good Practices

Authorship definition: significant intellectual contribution, not just technical one

No submission of previously published material

No simultaneous submission of same work to different journals

No public disclosure prior to publication or in keeping with embargos

Subjects protection compliance met

Data sharing a condition of publication

Deposit of archival data for public access a condition of publication

Disclosure and management of conflicts

Transfer of copyright to publisher

Club Rules of Authorship

- Publishers: Instructions to Authors
- Societies and Organizations: Guidelines for Authorship
- Institutions: Guidelines for Responsible Conduct

AUTHORSHIP GUIDELINES: ICMJE

http://www.icmje.org/

Vancouver Group, 1978

Commonly accepted guidelines for manuscripts submitted for publication

Now subscribed to by several hundred journals

Guidelines on many aspects of publication, including Authorship

AUTHORSHIP GUIDELINES: ICMJE

October 2007

1. All persons designated as authors should qualify for authorship
2. All those who qualify should be listed
3. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content
4. One or more authors should take responsibility for the integrity of the work as a whole, from inception to published article.

AUTHORSHIP GUIDELINES: ICMJE

Authorship credit based only on:
-substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data
-drafting the article or revising it critically for important intellectual content; and
-final approval of the version to be published

Authors should meet all three of these conditions

Insufficient grounds for authorship:
Acquisition of funding
collection of data
general supervision of the research group

- Editor Roles and Responsibilities
- Authorship
- Reviewer Roles and Responsibilities
- Sponsor Roles and Responsibilities
- Relations Between Editors and Publishers Sponsoring Societies, or Journal Owners
- Responsibilities to the Media
- Description of Research Misconduct
- International Models for Responding to Research Misconduct
- Reporting Suspect Manuscripts
- Digital Images and Misconduct
- Correcting the Literature
- Handling Third Party Inquiries About Scientific Misconduct

http://www.councilscienceeditors.org/editorial_policies/white_paper.cfm

Committees, Associations, and Organizations

The Council of Science Editors. This group began in 1957 as the Council of Biology Editors. Its mission is *to serve members in the scientific, scientific publishing, and information science communities by fostering networking, education, discussion, and exchange and to be an authoritative resource on current and emerging issues in the communication of scientific information*
http://www.councilscienceeditors.org/

Uniform Requirements for Manuscripts International Committee of Medical Journal Editors.
In 1978, a group of editors proposed uniform guidelines for publication in medical journals, including specific criteria for authorship. These guidelines for publication are periodically updated; the most recent update was February 2006. These guidelines may be accessed at:
http://www.icmje.org/index.html

Committee on Publication Ethics
[Formed in 1997] *COPE is a forum for editors of peer-reviewed journals to discuss issues related to the integrity of the scientific record; it supports and encourages editors to report, catalogue and instigate investigations into ethical problems in the publication process* (from their mission statement)
http://www.publicationethics.org.uk/

The World Association of Medical Editors
Established in 1995 to facilitate worldwide cooperation and communication among editors of peer-reviewed journals; this groups compiles resources and develops policies of relevance to authorship and publication practices. http://www.wame.org/

The HHS Office of Research Integrity: Resources on Publication Practices; e.g., responsible authorship, peer review, literature searching and more.
http://www.ori.hhs.gov/education/products/rcr_authorship.shtml

THE ROLE OF SCIENTIFIC SOCIETIES

Society for Neuroscience 1998; Guidelines: Responsible Conduct Regarding Scientific Communication.
http://www.sfn.org/index.cfm?pagename=responsibleConduct.

American Chemical Society 2006; Ethical Guidelines to Publication of Chemical Research.
http://pubs.acs.org/ethics/ethics.pdf.

American Society for Microbiology 2007; Instructions to Authors for ASM Journals.
http://www.journals.asm.org/misc/ifora.shtml.

Authorship Culture and Club Rules: Professional Society Policies

	APA (Psych)	SFN (Neurosci)	ICMJE (Med. Eds.)	ASM (Micro)	ACS (Chem)	ASCE (Civ. Eng.)	AGU (Geophys. Union)	ASHA (Am. Speech & Hearing Assoc.)
Tech. Contribution - Signif. Contribution	x	x	x	x	x	x	x	x
Copyright issues	x	(x)	x	x	x	x	x	x
COI	x	x	x	x	x	x	(x)	x
Duplicate Publication	x	x	x	x	x	x	x	x
Sharing Data	x	x		x			x	(x)

Club Rules of Authorship

- Publishers: Instructions to Authors
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- Institutions: Guidelines for Responsible Conduct

US Medical Schools with Guidelines Discussing Authorship

Year	Authorship Guidelines Reported	Respondents
1990	13%	99 (n=125)
1997	21%	unknown
2000	36%	99 (n=125)

Background, Trends and New Ideas

PNAS | **July 20, 2004** | vol. 101 | no. 29 | **10495**

Responsible authorship of papers in PNAS
Nicholas R. Cozzarelli, Editor-in-Chief

PNAS encourages authors describing contributions in a footnote. Examples of designations an author could note include the following:

- Designed research
- Performed research
- Contributed new reagents or analytic tools
- Analyzed data
- Wrote the paper

http://www.pnas.org/cgi/content/full/101/29/10495

Trends and New Ideas

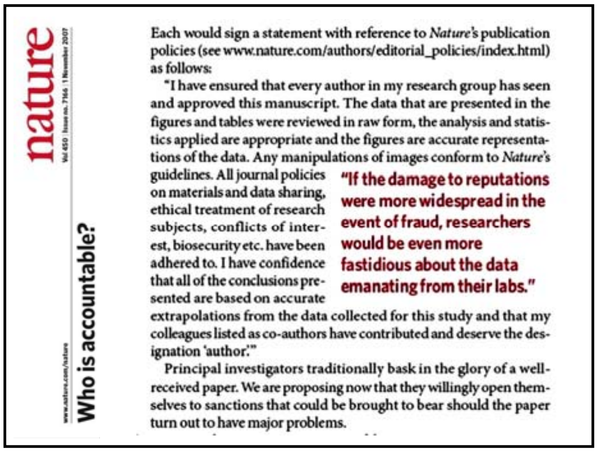
Contributorship model

F.L.M. was Principal Investigator of the study and provided oversight for the entire research project and manuscript development. C.L.F. was co-principal investigator and oversaw the survey development, analysis and interpretation of the data. K.A.B. was co-investigator and oversaw the sample management and data collection. All authors participated in the development of survey measures, data analysis and interpretation. F. L. M. wrote the case vignettes, the Introduction section and performed the literature search. K.A.B. and C.L.F. wrote the Methods section. C.L.F. performed the data analysis and wrote the Results section. F.L.M. and C.L.F. wrote the Discussion section. All authors co-edited the Introduction, Methods, Results and Discussion section. None of the authors have any financial, personal, or institutional conflicts of interest related to the performance of this research or the reporting of its results.

Guarantor model

•Who is accountable? (*Nature 11/1/07*)

•Order of Merit (*Nature 7/26/07*)


nature Vol 450 | Issue no. 7166 | 1 November 2007

Who is accountable?

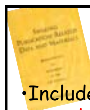
www.nature.com/nature

Each would sign a statement with reference to *Nature*'s publication policies (see www.nature.com/authors/editorial_policies/index.html) as follows:

"I have ensured that every author in my research group has seen and approved this manuscript. The data that are presented in the figures and tables were reviewed in raw form, the analysis and statistics applied are appropriate and the figures are accurate representations of the data. Any manipulations of images conform to *Nature*'s guidelines. All journal policies on materials and data sharing, ethical treatment of research subjects, conflicts of interest, biosecurity etc. have been adhered to. I have confidence that all of the conclusions presented are based on accurate extrapolations from the data collected for this study and that my colleagues listed as co-authors have contributed and deserve the designation 'author.'"

"If the damage to reputations were more widespread in the event of fraud, researchers would be even more fastidious about the data emanating from their labs."

Principal investigators traditionally bask in the glory of a well-received paper. We are proposing now that they willingly open themselves to sanctions that could be brought to bear should the paper turn out to have major problems.



Principles

•Include all that is necessary to support claims and reproduce work

•Central information justifiably not included in paper must be accessible and or made available in usable form

•Where agreed upon by community of researchers, data must appear in a publicly available database by the time of publication

•State in paper how to obtain likely requested materials, information on material transfer agreement

•Patented material should be made available under a license for research use http://www.nap.edu/catalog/10613.html

http://grants2.nih.gov/grants/policy/data_sharing/

http://www.nsf.gov/pubs/policydocs/gc1_607.pdf

NATIONAL SCIENCE FOUNDATION (NSF)
Grant General Conditions (GC-1)
June 1, 2007

(Sec. 7011) Makes an investigator supported under a NSF award, whom the Director determines has failed to comply with the provisions of section 734 (concerning the dissemination and sharing of research results) of the Foundation Grant Policy Manual, ineligible for a future award under any NSF supported program or activity. Allows the Director to restore the eligibility of such an investigator on the basis of the investigator's subsequent compliance with such provisions and with such other terms and conditions as the Director may impose. AMERICA COMPETES ACT of 2007

Recent Developments in Publication Practices

Biosecurity implications (4/12)

Clinical trials registration (all ICMJE)

Peer review and digital imaging (5/12)

Instructions to Authors

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2. Cell
3. Genetics
4. Journal of Bacteriology
5. Journal of Biological Chemistry
6. Journal of Dental Research
7. Journal of Experimental Medicine
8. Journal of Molecular Biology
9. Nature
10. New England Journal of Medicine
11. Proceedings of the National Academy (USA)
12. Science


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Caution About a Bioterror Attack on the U.S. Milk Supply

June 2006

STANFORD GRADUATE SCHOOL OF BUSINESS — A mere 4 grams of botulinum toxin dropped into a milk production facility could cause serious illness and even death for 400,000 people in the United States. Investments that would cost the public only 1 cent more per half-gallon of milk could prevent this nightmare scenario, according to Lawrence M. Wein of the Stanford Graduate School of Business.

Wein, the Paul E. Holden Professor of Management Science, has been conducting a series of studies on the effects of various potential terrorist activities in United States. Not only milk, but soft drinks, fruit and vegetable juices, processed tomato products, and even grains—anything that goes through large-scale storage and production and rapid distribution—could be at risk for such an attack, with catastrophic consequences for the American public, Wein says in his most recent study, conducted with Yifan Liu, a PhD candidate at the Institute for Computational and Mathematical Engineering at Stanford University.

Public Policy

Research by

Lawrence Wein
Paul E. Holden Professor of Management Science
Stanford Graduate School of Business

Yifan Liu
PhD Candidate
Institute for Computational and Mathematical Engineering
Stanford University

Questions about news and research: gsb_info@gsb.stanford.edu
(650) 723-3157

http://www.gsb.stanford.edu/news/research/pubpolicy_wein_bioterror.shtml

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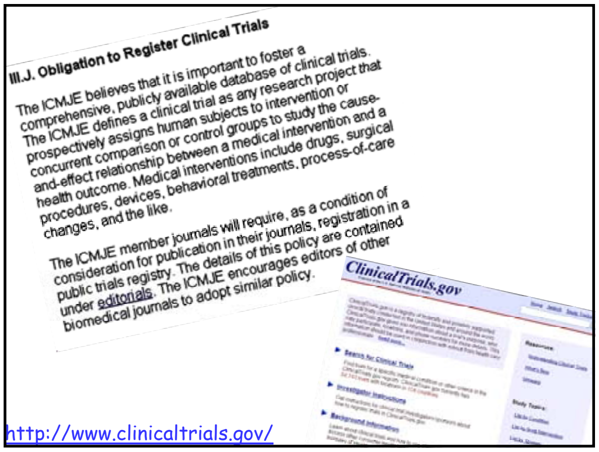
III.J. Obligation to Register Clinical Trials

The ICMJE believes that it is important to foster a comprehensive, publicly available database of clinical trials. The ICMJE defines a clinical trial as any research project that prospectively assigns human subjects to intervention or concurrent comparison or control groups to study the cause-and-effect relationship between a medical intervention and a health outcome. Medical interventions include drugs, surgical procedures, devices, behavioral treatments, process-of-care changes, and the like.

The ICMJE member journals will require, as a condition of consideration for publication in their journals, registration in a public trials registry. The details of this policy are contained under editorials. The ICMJE encourages editors of other biomedical journals to adopt similar policy.

http://www.clinicaltrials.gov/

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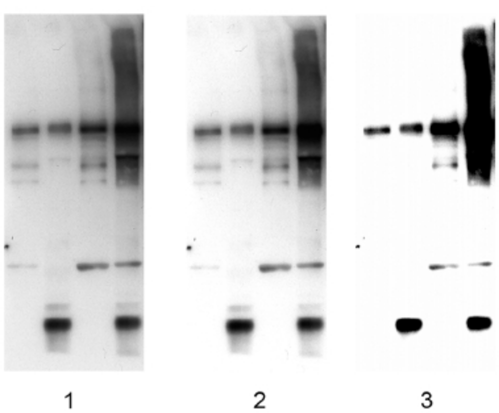
http://www.jcb.org/cgi/content/full/166/1/11



J. Experimental Medicine (Rockefeller Press)

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OPEN ACCESS PUBLICATION

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http://www.plos.org/

http://www.doaj.org/

http://publicaccess.nih.gov/

Parting Thoughts

Formality replacing folklore

Know where to find guidance on authorship and publication practices

Get involved

- be a good mentor and educate proactively
- be a good trainee: engage your mentor and colleagues
- be part of the process of developing policies and guidelines (e.g., your institution, your scientific society(s),

Jay Akash, a new assistant professor, is getting ready to submit his first paper since joining the faculty. He reviews one of the figures for his paper, which is an image of an ethidium bromide-stained agarose gel. The gel contains the products of PCR-amplified whole-cell DNA. The photograph displays the predicted 3-kb DNA fragment. Jay comments that a second, minor signal was also evident on the original gel. Based on its size, Jay believes that this second fragment represents a very exciting discovery, but it needs considerable additional work. This second fragment cannot be seen in the image. Jay discloses that this is because he has deliberately adjusted the contrast of the image using a computer editing program to obscure the second fragment. He says he did this because he is worried that competing groups in larger, more established labs will recognize the potential of the second fragment and will "scoop" him. He has prepared a figure legend that says: "a second, minor signal of unexplained origin was present in this experiment but is not visible in the photograph." But the figure legend does not indicate the size of the unexplained fragment. Thus, he argues he will be telling the truth while protecting himself from his competition. Are Jay's actions appropriate? Is he (i) simply playing fairly in the hotly competitive arena of biomedical research, (ii) falling victim to self-deception, or (iii) perpetrating scientific fraud?

Dr. Lynn Newell, a chemistry professor at a major university is the principal investigator of a large federal grant to study the properties of naturally occurring substances isolated from fungi that live in unusual environments. A novel fungus isolated by Chris Evans two years ago in Yellowstone National Park has been under study in Newell's lab ever since. A heat resistant form of the enzyme DNA ligase has been purified from it. This enzyme, which seals gaps in DNA strands, has been thoroughly characterized. The gene for it has been cloned and expressed in recombinant *Escherichia coli* allowing purification of large amounts of the enzyme. The nucleotide sequence of the DNA ligase gene has been determined and analyzed. This enzyme has sparked enormous intellectual and commercial interest. A heat resistant DNA ligase has never been reported in a fungus before, so this discovery creates interesting questions about molecular evolution, gene transfer, and DNA synthesis and repair. What's more, Newell and collaborators have designed a revolutionary genetic test using their heat resistant DNA ligase. They have demonstrated its utility in linking select stretches of DNA which may be diagnostic for certain genetic diseases. At the regular Friday noon meeting of all lab personnel and collaborators, Dr. Newell says it's time to prepare a manuscript describing these exciting results and submit it to the *Proceedings of the National Academy of Sciences*. Dr. Newell starts a discussion to decide whose names will appear on the author by-line of the paper (or alternatively in the acknowledgements). Newell asks everyone to describe their involvement in the work in order to begin a discussion about what contributions merit authorship on the paper.

Dr. Lynn Newell: university professor of chemistry, principal investigator (lab chief).

Dr. Kim Lee: a research assistant professor working under Dr. Newell.

Pat Langella: a 4th year predoctoral trainee; Dr. Newell is Langella's Ph. D. supervisor.

Chris Evans: an undergraduate student who is doing a multi-year honors project under Dr. Newell's guidance.

Brook Lovell: a Master's degree trainee working under Dr. Newell.

Dr. Fran McClure: an assistant professor in the department of chemistry whose area of research is enzymology.

Dr. Lynn Newell: "Good morning, everyone. As you may remember when this project began, we had some casual conversations about who would be authors on a paper, should the results be publishable. We now have some very exciting results and they certainly are publishable! So today, we need to get serious about who goes in the author's byline or in the acknowledgements. I asked you each to prepare a concise statement about your part in the work in order to get this ball rolling. Today we'll just arrive at who will be authors. We'll work out the order of the author's names on the byline at a later time. Let me begin with my comments.

I wrote the NIH grant proposal that provided funding for this work. The idea to look for a heat resistant DNA ligase was Fran McClure's and the idea to commercially apply this discovery was mine. These experimental approaches were described in my NIH proposal, but the work of the entire DNA ligase project was only a minor part of overall thrust of the work. And, I did not hypothesize a heat resistant ligase in the proposal. Dr. McClure provided a lot of the scientific guidance to others in the lab who did experiments on this project. I did no experimental work on this project but I insist on reading, editing, and approving the planned manuscript. Finally, as you're aware I'm Pat Langella's mentor.

Regarding authorship, I believe I should…."

Dr. Kim Lee: "After a long struggle, I cloned the DNA ligase gene as a "side project" during a break in my own research activities. I did a preliminary characterization of the cloned gene and made milligram amounts of the recombinant plasmid carrying the gene. I gave this plasmid material to Pat Langella, who performed the nucleotide sequence analysis of the DNA ligase gene. I did a small amount of the experimental work on this proposed assay at Sam Patterson's urging.

Regarding authorship, I believe I should…."

Pat Langella: "I am a 4th year predoctoral trainee. Although Dr. Newell is my formal academic advisor, much of my laboratory mentoring is provided by Fran McClure. McClure is always available to provide guidance and critique my work. I purified and characterized the enzyme with my own hands, and completed the nucleotide sequence of the gene. I plan to write the entire first draft of the manuscript, including composing all the data tables and manuscript drawings. I will do the literature search needed to critically review the field. Eventually, this manuscript will become a chapter in my Ph.D. dissertation.

Regarding authorship, I believe I should…."

Chris Evans: "I am doing an undergraduate honors project under Dr. Newell's supervision. I and my family spent our vacation in Yellowstone two years ago and Dr. Newell asked me to bring back some water samples and fungal specimens from the hot springs for my honors project. One of the fungus isolates I cultivated from these samples yielded the heat resistant DNA ligase. I did all the necessary taxonomic work to identify this fungus and stocked it in Dr. Newell's culture collection.

Regarding authorship, I believe I should…."

Brook Lovell: "I am working towards a Master's degree in Dr. Newell's lab. I have a B.S. degree and extensive experience in bioinformatics. I taught Pat Langella how to use several computer programs to analyze DNA and protein sequence information. Pat used this training to do all the computer analyses on the gene and to do a preliminary analysis on the protein product. On several occasions I helped Pat interpret the sequence information. My five weeks of instruction provided to Pat were equivalent to a 2 credit hour course. I also helped Pat learn a complex computer graphics programs for illustrating sequence data.

Regarding authorship, I believe I should…."

Dr. Fran McClure: "I had the original idea to look for a heat resistant DNA ligase. I suggested several sources for isolating enzymes from lower plants living in extreme conditions. I designed the enzyme purification scheme, and supervised Pat Langella in this aspect of the work. I critiqued all data involving the enzyme isolation and purification. On several occasions, I suggested new experimental approaches to the enzyme purification, all of which proved fruitful.

Regarding authorship, I believe I should…."

http://www.courses.vcu.edu/rcr/