



## Instructions to Authors

### *Codes*

- Copyright information
- Conflict of interest
- Prior publication policy

### *Conduct and etiquette*

- Criteria for authorship
- Responsibilities of authorship
- Policy on sharing research materials and archival data
- Properly citing the literature: correct and useful references

## Instructions to Authors

### *Housekeeping and Logistics*

- Details for manuscript preparation
- Manuscript review: process and policy
- Unpublished information and personal communications policies
- Handling imperfections : disputes, corrections, errata, retractions

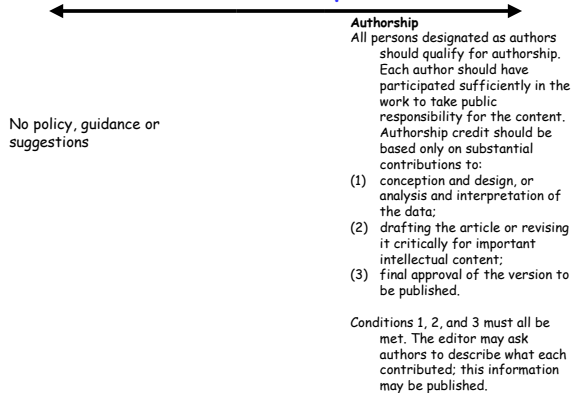
## Instructions to Authors

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*

## Summary of Guidance in IFAs

	1975	1985	2003
Au definition	0%	8%	33%
Au read and approve	0%	25%	75%
Conflict of Interest	0%	8%	50%
Copyright	16%	25%	75%
Human use	8%	16%	67%
Animal use	8%	16%	67%

## IFA Information Spectrum



## International Journal of Radiation Oncology, Biology and Physics

	1975	1985	1995
Exclusive submission	"...original papers must be contributed solely to the journal...and may not be published elsewhere...without written permission"		
"Author is responsible for all statements in his work, including changes made by the copy editor."			
"Accepted manuscripts become the property of the journal..."			
Financial support disclosure: "...state...source of financial support..."			
"...statement that informed consent was obtained after the nature of the procedure(s) was fully explained."			
Patient confidentiality: "...identities of patients should be masked; [or] ...permission letters must accompany patient photos..."			
"The author must obtain permission from the previous author and the copyright holder to reproduce illustrations previously published"			
"Authors are responsible for bibliographic accuracy"			

**International Journal of Radiation Oncology, Biology and Physics 2004**

Exclusive submission

"It is a condition of publication that manuscripts...have not been published and will not be simultaneously submitted or published elsewhere."

Author responsible for all statements

"Any change in authorship following submission...explained in a letter...signed by all co-authors..."

Financial support disclosure

"...[tell editor]...any information that might affect consideration of the manuscript; [might include] disclosures of financial or other interests.."

journal adheres to policy on "conflict of interest promulgated by the ICMJE" which says: "authors must state explicitly whether potential conflicts do or do not exist..."

Informed consent obtained

"...indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation, and with the Helsinki Declaration..."

"...experiments on animals, the authors must indicate whether the institution's or a national research council's guide for, or any national law on, the care and use of laboratory animals was followed."

Patient confidentiality

"...patient anonymity must be ensured...do not use patient names, initials, hospital numbers, or other identification..."

Permission to use previously published material

**Club Rules of Authorship**

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

**American Chemical Society Guidelines: Authorship Ethics**

<http://pubs.acs.org:80/instruct/ethic.html>

- write an accurate account of work and objective discussion of significance
- present sufficient detail and necessary reference to allow peers to repeat work
- reasonable sharing of research materials unavailable elsewhere; appropriate material transfer agreements
- appropriate citation of references
- avoid fragmentation of research reports
- inform editor of related manuscripts (in press or submitted) and supply to editor
- no duplicative submissions (OK to expand a "letter" or "communication" into a full paper, but fully disclose this)

**Responsible Conduct in Scientific Communication**

**Society for Neuroscience**  
<http://www.sfn.org/guidelines/>

1. **Authors of Research Manuscripts**
  - 1.1. Authors are encouraged to have the first formal publication of their results be a peer-reviewed paper.
  - 1.2. Manuscripts should be prepared to maximize clarity and accuracy of communication.
  - 1.3. Authorship should be based on a substantial intellectual contribution.
  - 1.4. "Honorary authorship" is inconsistent with the definition of authorship.

**AUTHORSHIP GUIDELINES: ICMJE**

Vancouver Group, 1978

Commonly accepted guidelines for manuscripts submitted for publication

Now subscribed to by over 500 journals

Guidelines on many aspects of publication, including Authorship

## AUTHORSHIP GUIDELINES: ICMJE

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

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

## AUTHORSHIP GUIDELINES: Contributorship Model

**Council of Biology (Science) Editors**  
Authorship Task Force, 2000  
Contributorship Model :  
Identify contribution(s) of each author

**Authorship Task Force:**  
"To help restore a sense of proportion and confidence in the validity of biomedical publication, this conference proposes a new step in the evolution of the concept of authorship. We propose to publish the contributions of the individuals associated with a manuscript." (Friedman, 2000)

## AUTHORSHIP GUIDELINES: Contributorship Model

Now used by several journals:  
American Journal of Public Health  
Annals of Internal Medicine  
British Medical Journal  
Lancet  
Radiology

Example (Authorship):  
Pietro Scillia, Sophia Abdel Kafi, Christian Mélot, Caroline Keyzer, Robert Naeije, and Pierre Alain Gevenois (2001): Oleic Acid-induced Lung Injury: Thin-Section CT Evaluation in Dogs. *Radiology* 219:724-731.

## AUTHORSHIP GUIDELINES: Contributorship Model

Example (Contributorship):  
Author contributions: Guarantor of integrity of entire study, P.S., R.N., P.A.G.; study concepts, P.S., P.A.G.; study design, S.A.K., P.S.; literature research, P.S.; experimental studies, P.S., S.A.K., C.M., C.K., P.A.G.; data acquisition, P.S., S.A.K., C.M., C.K., P.A.G.; data analysis/interpretation, P.S., S.A.K., R.N., P.A.G.; statistical analysis, P.S., C.M.; manuscript preparation, P.S.; manuscript definition of intellectual content, P.S., R.N., P.A.G.; manuscript editing, P.S.; manuscript revision/review, R.N., P.A.G.; manuscript final version approval, all authors.

**MUTATIONS OF BACTERIA FROM VIRUS SENSITIVITY TO VIRUS RESISTANCE<sup>1</sup>**  
S. E. LERIVÉ and M. DELBRUCK  
*Indiana University, Bloomington, Indiana, and  
Foodbook University, Nashville, Tennessee*  
Received May 29, 1942

INTRODUCTION

WHEN a pure bacterial culture is attacked by a bacterial virus, the culture will clear after a few hours due to destruction of the sensitive cells by the virus. However, after further inoculation for a few hours, or sometimes days, the culture will often become turbid again, due to the growth of a bacterial variant which is resistant to the action of the virus. This variant can be isolated and freed from the virus and will in many cases retain its resistance to the action of the virus even if subcultured through many generations in the absence of the virus. While the sensitive strain understood the virus readily, the resistant variant will generally not show any affinity to it.

The resistant bacterial variants appear readily in cultures grown from a single cell. They were, therefore, certainly not present when the culture was started. Their resistance is generally rather specific. It does not extend to viruses that are found to differ by other criteria from the strain in whose presence the resistant culture developed. The variant may differ from the original strain in morphological or metabolic characteristics, or in serological type or in colony type. Most often, however, no such correlated changes are apparent, and the variant may be distinguished from the original strain only by its resistance to the inoculating strain of virus.

The nature of these variants and the manner in which they originate have been discussed by many authors, and numerous attempts have been made to correlate the phenomenon with other instances of bacterial variation.

The net effect of the addition of virus consists of the appearance of a variant strain, characterized by a new stable character—namely, resistance to the inoculating virus. The situation has often been expressed by saying that bacterial viruses are powerful "dissociating agents." While this expression is unambiguously adequate to the net effect, it must not be taken to imply anything about the mechanism by which the result is brought about. A moment's reflection will show that there are greatly differing mechanisms which might produce the same end result.

OPPERBAUM (1941) and many other investigators believed that the virus by direct action induced the resistant variants. GRATH (1931), BRUNDT (1936), and others, on the other hand, believed that the resistant bacterial variants are produced by mutation in the culture prior to the addition of virus. The

1 Theory by M. D., experiments by S. E. L.

2 From the Department of Microbiology, Indiana University, and from the Foodbook University, Nashville, Tennessee.

3 Journal of the Bacteriological Association.

**A Slot Machine, A Broken Test Tube**  
An Autobiography  
S.E. Luria

*Theory by M. D., experiments by S. E. L.*

## Club Rules of Authorship

- Publishers: Instructions to Authors
- Societies and Organizations: Guidelines for Authorship
- 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)

## Survey of accredited US medical schools:

99 respondents/125 institutions  
 98 had guidelines for research conduct  
 36/98 had publication components  
 34/98 had authorship components

<http://ori.dhhs.gov/html/publications/analysisofguidelinesfortheconduct.asp> 2001

## Number of Guidelines Discussing Each Content Area:

Content Area	Number of Guidelines
<b>Publication Practices</b>	
A. Multiple Submissions/Duplicate Publications	14
B. Inclusion of Fragmented, Preliminary, or Unpublished Data	10
C. Corrections and Retractions	1
D. Acknowledgments	4
<b>Authorship</b>	
A. Qualifications for Authorship	23
B. Responsibilities of Authorship	31
C. Gift, Honorary, or Ghost Authorship	9
D. Order of Authorship	9
E. Textbook Authorship Issues	1
<b>Peer Review</b>	
A. Responsibilities of Reviewers	4
B. Conflict of Interest	3
C. Treatment of Confidential Information	5

## Cases for Discussion

## Conflict of Interest

## Conflict of Interest

An obligation or commitment to two or more competing interests that creates the **perception** or the **reality** of an increased risk of bias or poor judgment.

## COI Take Home Lessons

Policy

Perception

Family

Action

## Conflict of interest --

This term has become synonymous with monetary or personal gain (legal origin)

It encompasses behaviors or actions in which someone (or a member of their immediate family or household) gains personally or financially as the result of that person exploiting his or her position.

## Conflict of effort (or commitment) --

"a person who accepts full time employment to a faculty or research position, or status as a full time research fellow or student of [the university] has an obligation to devote his/her primary professional effort and allegiance to the university. Other activities or commitments should be arranged so as not substantially to conflict with or dilute this commitment."

## Conflict of effort—

- the university encourages faculty to engage in public service, public relations, and entrepreneurship
- faculty can devote effort to endeavors of little relevance to the mission of the institution at the expense of their primary duties and responsibilities
- academic freedom vs. academic integrity

## Conflict of conscience—

A conflict created by maintaining objectivity in the face of your convictions which go against the grain of something you must act on or evaluate.

## COMPETING INTERESTS

Who is harmed?

Distortion of institutional mission  
 Undue influence for personal gain  
 Distortion of scientific record  
 Faulty regulatory decisions  
 Unfair treatment of others  
 Risks to human subjects  
 Loss of Public Trust

## DISCLOSURE OF POTENTIAL CONFLICTS IN THE RESEARCH LITERATURE

Krimsky, Rothenberg, Stott, and Kyle, 1998. Scientific journals and their authors' financial interests: A pilot study. *Psychother Psychosom* 1998 Jul-Oct;67(4-5):194-201

Goozner, M. 2004. Unrevealed: non disclosure of conflicts of interest in four leading medical scientific journals. <http://cspinet.org> (web site of the Center for Science in the Public Interest)

### Experimental Design for Evaluating COI Disclosure

Investigators Report & Date	Krimsky et al Psychother Psychosom 1998	Goozner Gen. Sci. Pub. Int web site 2004
Study time frame	1992	Dec 2003-Feb 2004
Author pool	Mass. acad. Scientists	unrestricted
No. journals Used	14	4
No. articles	789	163
COI guidelines published by journals	generally no	all have detailed guidelines
Info potential COIs	public databases	public databases

### Results

Investigators Report & Date	Krimsky et al Psychother Psychosom 1998	Goozner Gen. Sci. Pub. Int web site 2004
Freq. unreported COIs	34%	8%
Other info	0.5% of 1,474 <i>Lancet</i> articles had disclosures (93-96)	
Conclusions	COI disclosures are under-reported	Narrow definitions of COI may contribute -authors rationalize -editors misinterpret

### Feeling the Heat, NIH Tightens Conflict-of-Interest Rules

As the House dove into a third hearing on consulting by National Institutes of Health scientists, NIH Director Elias Zerhouni last week pledged to make "drastic changes" to the policies as part of reforming the agency. The changes would include a ban on outside awards, and a ban on outside activities on the Internet. The House panel lauded these steps but topped a bombshell: It claims to have evidence that some NIH researchers may have ignored rules requiring them to report their consulting activities. The House panel questioned NIH scientists (Science, 21 May, p. 1091). NIH and its employees have insisted that they followed the rules.

**Recent Press**

**Zerhouni's Ethics Clampdown**

<b>Blue-ribbon panel recommendation</b> No industry consulting by senior officials or staff overseeing extramural funding decisions Staff consulting limited to 50% of annual salary (100% for clinicians); 400-hour annual limit No stock options as consulting payments More employees should file publicly available financial reports No limits on bona fide awards	<b>NIH proposed additions</b> No staff can serve on corporate boards; service on advisory board requires high-level review; no paid consulting for grantee institutions Staff consulting fees limited to 25% of annual salary; clinicians limited by local market rates Employees who file financial reports cannot own any stock in drug or biotech companies Outside activity details will be disclosed in a public database on the Internet Only awards on approved list allowed; senior officials overseeing funding to entity giving award cannot receive cash portion
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**Science**  
2 July

Cash awards to NIH scientists may be restricted, too. The committee had questioned a \$40,000 prize from the University of Pittsburgh to former National Cancer Institute (NCI) Director Richard Klausner, given after NCI helped the university settle a lawsuit. Now, NIH will "scrub every award out there," Zerhouni said, compile a list of bona fide awards, and screen every

### Zerhouni's Ethics Clampdown

<b>Blue-ribbon panel recommendation</b> No industry consulting by senior officials or staff overseeing extramural funding decisions Staff consulting limited to 50% of annual salary (100% for clinicians); 400-hour annual limit No stock options as consulting payments More employees should file publicly available financial reports No limits on bona fide awards	<b>NIH proposed additions</b> No staff can serve on corporate boards; service on advisory board requires high-level review; no paid consulting for grantee institutions Staff consulting fees limited to 25% of annual salary; clinicians limited by local market rates Employees who file financial reports cannot own any stock in drug or biotech companies Outside activity details will be disclosed in a public database on the Internet Only awards on approved list allowed; senior officials overseeing funding to entity giving award cannot receive cash portion
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## Institutional policies

Typically university guidelines say:

- 1) no interference with primary job
- 2) activities should serve faculty member's interests;
- 3) 20% time: 1 working day/week); disclosure to supervisor (planned, anticipated, accomplished);
- 4) prior approval for activities that require more than an occasional day or two at infrequent intervals.

NATIONAL INSTITUTES OF HEALTH  
Office of Extramural Research **Funding agency policy**

Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought

NIH Funding Opp (Authority: 42 U.S.C. 216, 289b-1, 299c-3) and Guidelines

"Investigator" includes the Investigator's spouse and dependent children.

"Significant Financial Interest" means anything of monetary value, including but not limited to:

- salary
- consulting fees or honoraria
- equity interests
- intellectual property rights

Additional links: Selected Grant Programs, Laboratory Animal Welfare (PLAW), Human Subjects (HHS), Intellectual Property Policy, Peer Review Policy and Issues, eRA Home Page, NIH Commons, Edison Invention Reporting, About OER - OER Resources, Introduction to Extramural Research from Dr. Norka Ruiz-Blanco.

Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought  
(Authority: 42 U.S.C. 216, 289b-1, 299c-3)

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<http://grants.nih.gov/grants/guide/notice-files/not95-179.html>

Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought  
(Authority: 42 U.S.C. 216, 289b-1, 299c-3)

The term does not include:

- remuneration from the applicant institution;
- ownership interests in the institution, if the institution is an applicant under the SBIR Program
- income from seminars, lectures, or teaching engagements sponsored by public or nonprofit entities;
- income from service on advisory committees or review panels for public or nonprofit entities
- equity interest that when aggregated for the Investigator and the Investigator's spouse and dependent children, meets both of the following tests:
  - does not exceed \$10,000 in value and does not represent more than a five percent ownership interest in any single entity
- salary, royalties or other payments that when aggregated for the Investigator and the Investigator's spouse and dependent children over the next twelve months, are not expected to exceed \$10,000.

Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought

### Institutional Responsibilities

- maintain and policy on conflict of interest and inform investigators of it
- apply policy to subgrantees, contractors, etc.
- enforce policy

Designated official(s) to review disclosure statements that must be filed by the time PHS grant applications are submitted

Provide Guidelines for taking action on conflicts

Maintain records

Establish adequate enforcement

Certify all of the above in submitting applications

Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought

### Management of Conflicting Interests

The designated official(s) must: review all financial disclosures; and determine whether a conflict of interest exists and, if so, determine what actions should be taken by the institution to manage, reduce, or eliminate such conflict of interest. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the PHS-funded research.



**Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought**

**Management of Conflicting Interests**

Examples of conditions or restrictions that might be imposed to manage conflicts of interest include, but are not limited to:

- (1) public disclosure of significant financial interests;
- (2) monitoring of research by independent reviewers;
- (3) modification of the research plan;
- (4) disqualification from participation in all or a portion of the research funded by the PHS;
- (5) divestiture of significant financial interests;
- (6) severance of relationships that create actual or potential conflicts.

**Financial Relationships in Clinical Research: Draft Guidance**

- Who is the sponsor?
- Who designed the clinical trial?
- Who will analyze the safety and efficacy data?
- Is there a Data Safety Monitoring Board (DSMB)?
- What are the financial relationships between the Clinical Investigator and the commercial sponsor?
- Is there any compensation that is affected by the study outcome?
- Does the Investigator have any proprietary interests in the product (patents, trademarks, etc.)

•Does the Investigator have equity interest in the company-- publicly held company or non-publicly held company?

•Does the Investigator receive significant payments of other sorts? (e.g. grants, compensation in the form of equipment, retainers for ongoing consultation, and honoraria)

•What are the specific arrangements for payment?

•Where does the payment go? To the Institution? To the Investigator?

•What is the payment per participant? Are there other arrangements?

**Publisher's Policies**

**THE LANCET**

**Conflict of interest and source of funding**-- A conflict of interest exists when an author or the author's institution has financial or personal relationships with other people or organizations that inappropriately influence (bias) his or her actions. Financial relationships are easily identifiable, but conflicts can also occur because of personal relationships, academic competition, or intellectual passion. A conflict can be actual or potential, and full disclosure to The Editor is the safest course. All submissions to *The Lancet* must include disclosure of all relationships that could be viewed as presenting a potential conflict of interest (see *Lancet* 2001; **358**: 854-56). The Editor may use such information as a basis for editorial decisions, and will publish such disclosures if they are believed to be important to readers in judging the manuscript.

**Role of the funding source** All sources of funding should be declared as an acknowledgment at the end of the text. At the end of the Methods section, under a subheading "Role of the funding source", authors must describe the role of the study sponsor(s), if any, in study design; in the collection, analysis, and interpretation of data; in the writing of the report; and in the decision to submit the paper for publication. If there is no Methods section, the role of the funding source should be stated as an acknowledgment. If the funding source had no such involvement, the authors should so state.

**Conflict of interest statements for authors** At the end of the text, under a subheading "Conflict of interest statement", all authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of financial conflicts include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications, and travel grants, all within 3 years of beginning the work submitted. If there are no conflicts of interest, authors should state that there are none. The corresponding author should state that he or she had full access to all the data in the study and had final responsibility for the decision to submit for publication. For Commentaries, Seminars, Reviews, and Series, *The Lancet* may decide not to publish on the basis of a declared financial interest of an author in a company (or its competitors) that makes a product discussed in the paper. However, we would much prefer such matters to be resolved earlier, at the commissioning stage.

## What should we do about conflicts of interests?

### CONFLICTS OF INTEREST SHOULD BE AVOIDED OR MINIMIZED

•Although it is not possible to avoid all sources of conflict, it is in the **best interests** of the community of science and the individual scientist **to recognize conflicts of interest and to take steps to nullify** (e.g., sell shares in the company, turn down the research support, abandon the project) **or mitigate** those conflicts.

### CONFLICTS OF INTEREST SHOULD BE DISCLOSED

•If conflicts cannot be avoided, then those **conflicts should be disclosed**. As a minimum, the institution and any other parties with a substantive interest should be made aware of the extent and nature of the conflict. This includes the audience at meeting presentations and journal editors, whether in submitting or refereeing manuscripts.

### CONFLICTS OF INTEREST SHOULD BE MANAGED TO MINIMIZE BIAS

•**Disclosure is often not sufficient** because of the risks of bias, the temptation for irresponsible conduct, public and regulatory concerns about the possibility of misconduct, and the appearance of impropriety. For every step of the research process, **attempts should be made to isolate the conflicted individual(s) from all decisionmaking functions**.

### CONFLICTS OF COMMITMENT SHOULD BE RECOGNIZED, MINIMIZED, AND MANAGED

•For reasons similar to those described for conflicts of interest, every effort should be made to:

- (a) recognize conflicts of commitment;
- (b) attempt to eliminate or minimize those conflicts (e.g., discontinue non-academic activities or limit such activities to a few hours on the weekend); and
- (c) find mechanisms to manage any conflicts they cannot be sufficiently minimized (e.g., disclose conflicts to responsible university officials and arrange a mutually agreeable system for tracking of time and effort).

## Cases for Discussion

[back](#)

A computer scientist and a radiologist, both faculty at an academic medical center, have enjoyed a productive collaboration involving the development of a software program to evaluate abdominal tumors that have been visualized using magnetic resonance imaging (MRI). The computer scientist authored all of the computer source code and tested it using archived MRI files. The radiologist designed and carried out the clinical trial, and also provided guidance in this testing phase, allowing the computer scientist to refine and to ultimately perfect the program. Although both collaborators are elated by the fruits of their labors, they have become perplexed over how to publish their results. They recognize that the prime thrust of the manuscript will be the design and creation of the software, and this is not likely to be of interest to clinicians and physician-scientists. Such individuals will be mainly concerned with the application of the program and the clinical results. But these collaborators are well aware of the publication guidelines of journals in their disciplines: most strictly prohibit the publication of the same material in two different journals. The collaborators agree there is no single journal that give them the necessary coverage to both the computing scientist and the clinician researcher. They also know that splitting the data into two papers aimed at two different audiences will diminish the impact and possibly the utility of their work. They come to you for advice. What do you tell them? (© F. L. Macrina, 2004). [back](#)

Dr. Colleen May is a participating neurologist in a clinical trial to assess the efficacy and toxicity of a new anticonvulsant medication. For the duration of the two-year study, each neurologist is to meet with each of his or her patients for an average of 30 minutes each month. In Dr. May's case, this amounts to an average of 20 hrs/month. During each visit, the physicians administer a variety of specialized tests, requiring judgments dependent on their experience and training in neurology. At the completion of the study, the results are to be unblinded and analyzed by the project leaders. It is anticipated that at least 2 publications will be prepared for the *New England Journal of Medicine*. Dr. May has just learned that she will be listed in the acknowledgements, but not as an author of the manuscript. Dr. May argues that she has provided nearly 500 hours of her expert time, far more than needed to complete a publishable study in her experimental laboratory. Does Dr. May have a case for authorship? (© ASM Press, 2000; used with permission) [back](#)

Boris Pickett is a bioengineering graduate student at Upscale University. Under the supervision of his predoctoral mentor, Dr. Norman Bates, Boris has developed a novel feedback control loop and software implementation for image-guided radiotherapy. The study has been funded in part by the National Cancer Institute. Bates and Pickett have co-authored 2 published papers on the subject. They are now preparing to launch a clinical trial to evaluate their system. Unbeknownst to Dr. Bates, Boris' father, a physicist, is an inventor on the patent that covers the feedback algorithm in the most widely used image-guided frameless stereotactic radiosurgery delivery system. The patent is held by a small company and Boris' father makes about \$70,000 a year in royalties. In addition, Boris' father was given founder's stock in the company and these equity shares are now worth about 4 million dollars. These shares were placed in a trust fund for Boris several years ago, a fact that Boris is aware of. Boris is agonizing over whether to tell Dr. Bates about these issues. Are there any conflict of interest issues looming if Boris engages in the clinical testing of the new system? If so, discuss what are they and how they can be ethically and legally managed. (© F. L. Macrina, 2004). [back](#)