



# **CSE's White Paper on Promoting Integrity in Scientific Journal Publications**

*Editorial Policy Committee (2005–2006),  
Council of Science Editors*

[www.CouncilScienceEditors.org](http://www.CouncilScienceEditors.org)



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The full text of the White Paper with updated content can be accessed without charge through the Internet by going to the following URL: [http://www.councilscienceeditors.org/editorial\\_policies/white\\_paper.cfm](http://www.councilscienceeditors.org/editorial_policies/white_paper.cfm).



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## 1.0 INTRODUCTION

The Council of Science Editors and its Editorial Policy Committee encourage everyone involved in the journal publishing process to take responsibility for promoting integrity in scientific journal publishing. This paper will serve as a basis for developing and improving effective practices in achieving that goal.

Through this White Paper and other activities, the Editorial Policy Committee aims to open dialogue about ethical publishing practices, inform those involved in the editorial process, and foster informed decision-making by editors. We intend to work with other professional organizations to shape the scientific journal environment so that the integrity of our publications is upheld. With the understanding that what may be appropriate for one discipline or organization may not be so for another, the White Paper intends to inform and guide rather than direct. Because there is more published information available from the biomedical community on some of the topics in this paper, more references or examples in those areas are given. However, our intention is to provide information that is useful to all the sciences. To provide useful and practical support to journal editors, your input is needed to further develop this living document by pointing out areas that need to be expanded or updated. We will build on the work of this White Paper through the continued work of the Committee and your contributions. Please send comments and suggestions to [CSE@CouncilScienceEditors.org](mailto:CSE@CouncilScienceEditors.org) and include “Editorial Policy Committee” in the subject line.

*(Authorship: Diane Scott-Lichter took the lead in writing this section of the white paper on behalf of the CSE Policy Committee. Members of the Policy Committee and the CSE Board of Directors reviewed and commented on it. This section was formally approved by the CSE Board of Directors on September 13, 2006.)*



## 2.0 ROLES AND RESPONSIBILITIES IN PUBLISHING

### 2.1 Editor Roles and Responsibilities

Editors of scientific journals have responsibilities to the public, the scientific community as a whole, the owners/publishers of their journals, the authors who provide the content of the journals, the peer reviewers who comment on the suitability of manuscripts for publication, and the journal's readers.

Some **editor responsibilities to authors** are listed below.

- Providing guidelines for preparing and submitting manuscripts.
- Establishing and enforcing authorship criteria.
- Treating all authors with fairness, courtesy, objectivity, and honesty.
- Establishing and defining policies on conflicts of interest.
- Protecting the confidentiality of every author's work.
- Establishing a system for effective and rapid peer review.
- Making editorial decisions with reasonable speed and, when the manuscript is potentially appropriate for the journal, with input from peer reviewers who have adequate expertise to judge the manuscript, and communicating these decisions to authors in a constructive and helpful manner.
- Establishing clear guidelines for authors regarding acceptable practices for sharing information before and after publication.
- Establishing a procedure for reconsidering editorial decisions (see 2.1.9).
- Describing, implementing, and regularly reviewing policies for handling ethical issues and allegations or findings of misconduct by authors (see 2.1.10 and part 3).
- Informing authors of solicited manuscripts that the submission will be evaluated according to the journal's usual procedures or outlining the decision-making process if it differs from those procedures.
- Developing mechanisms to ensure timely publication of accepted manuscripts (see 2.1.6).
- Clearly communicating all other editorial policies and standards.

An editor's responsibility to the public now includes consideration of publication of content that may have "dual use." According to the National Science Advisory Board for Biosecurity (NSABB), "dual use research encompasses biological research with legitimate scientific purpose, the results of which may be misused to pose a biologic threat to public health and/or national security." To enhance biosecurity, the NSABB has been created to advise and assist with the development of guidelines in this area. Although this work is in early



stages, the NSABB site (<http://www.biosecurityboard.gov/index.asp>) is a source of information.

The following are examples of editorial policies and standards that editors may require of submitting authors.

- State all sources of funding for research and include this information in the acknowledgment section of the submitted manuscript.
- State in the manuscript, if appropriate, that the research protocol was approved by the relevant institutional review boards or ethics committees for human (including use of human cells or tissues) or animal experiments and that all human subjects provided appropriate informed consent.
- State in the manuscript, if appropriate, that regulations concerning the use of animals in research, teaching, and testing were adhered to. Governments, institutions, and professional organizations have statements about the use of animals in research. For example, see statements from the Federation of American Societies for Experimental Biology (<http://opa.faseb.org/pages/PolicyIssues/animalresearch.htm>), the Canadian Council on Animal Care ([http://www.ccac.ca/en/CCAC\\_Programs/Guidelines\\_Policies/POLICIES/TERMS00E.HTM](http://www.ccac.ca/en/CCAC_Programs/Guidelines_Policies/POLICIES/TERMS00E.HTM)), and, for links to other informational sites, the University of California, San Francisco (<http://www.research.ucsf.edu/arc/index.asp>).
- When race/ethnicity is reported, define who determined race/ethnicity, whether the options were defined by the investigator and if so what they were, and why race/ethnicity is considered important in the study.
- List contributors who meet the journal's criteria for authorship and identify other contributors (eg, statistical analysts, writers), with contributors' approval, in the acknowledgment section.
- Reveal any potential conflicts of interest of each author either in the cover letter, manuscript, or disclosure form, in accordance with the journal's policy. (An example of a disclosure form can be found at: <http://jama.ama-assn.org/cgi/data/295/1/103/DC1/1>.)
- Include (usually written) permission from each individual identified as a source for personal communication or unpublished data.
- Describe and provide copies of any similar works in process.
- Provide copies of cited manuscripts that are submitted or in press.
- Supply supporting manuscript data (eg, actual data that was summarized in the manuscript) to the editor when requested.
- Share data or other materials needed with other scientists in order to replicate the experiment. As an example, the instructions to authors of the *Proceedings of the National Academy of Sciences* (<http://www.pnas.org/misc/iforc.shtml>) state: "To allow others to replicate and build on work published in PNAS, authors must make materials, data, and associated protocols available to readers. Authors must disclose upon submission of the manuscript any restrictions on the availability of materials or information."





- Cite and reference other relevant published work on which the submitted work is based.
- Obtain permission from the copyright owner to use/reproduce his or her content (eg, figures and tables), in the submitted manuscript, if applicable. (An example of a copyright permission form can be found at: <http://www.biophysics.org/publications/copyright.pdf>.)
- Provide written permission from any potentially identifiable individuals referred to or shown in photographs in the manuscript.

Some journals may also request or require the following:

- Copyright transfer statement or licensing agreements. (See [http://jpet.aspetjournals.org/misc/JPET\\_copyright\\_form.pdf](http://jpet.aspetjournals.org/misc/JPET_copyright_form.pdf) for an example.)
- Statements from named third parties who are listed as having contributed to the study but who did not meet criteria for authorship.
- Adherence to the CONSORT statement (<http://www.consort-statement.org/>) that helps standardize reports of randomized trials. .
- STARD flow diagram and checklist (<http://www.clinchem.org/cgi/content/full/49/1/1>) for reporting diagnostic tests.
- Registration information for clinical trials. (Some guidelines can be found at: <http://jama.ama-assn.org/cgi/content/full/292/11/1363>. See also CSE's endorsement statement of the ICMJE policy ([http://www.councilscienceeditors.org/services/cse\\_editorial\\_policies.cfm#Paragraphnine](http://www.councilscienceeditors.org/services/cse_editorial_policies.cfm#Paragraphnine)) regarding clinical trial registration.)
- Compliance with MOOSE guidelines (<http://jama.ama-assn.org/cgi/content/full/283/15/2008>) for reporting meta-analyses and systematic reviews of observational studies.
- Adherence to QUOROM guidelines (<http://www.consort-statement.org/QUOROM.pdf>) for reporting meta-analyses and systematic reviews of randomized controlled trials.
- Adherence to the MIAME standards ([http://www.mged.org/Workgroups/MIAME/miame\\_1.1.html](http://www.mged.org/Workgroups/MIAME/miame_1.1.html)) for reporting microarray experiments.

Editors are also responsible for monitoring and ensuring the fairness, timeliness, thoroughness, and civility of the peer-review editorial process.

Peer review by external reviewers with the proper expertise is the most common method to check manuscripts for quality. However, editors may sometimes reject manuscripts without external peer review in order to make the best use of the journal's resources. Reasons for this practice usually include the following: the manuscript is outside the scope of the journal, is of poor quality and/or limited scientific merit, lacks originality or novel information, or has been previously published.

Reviewers are chosen by the editors. Many journals follow the practice of keeping reviewer identities anonymous to the authors (single masked), but





some journals give reviewers the option to reveal their names and other journals provide authors with the names of all reviewers associated with the manuscript. Some journals attempt to mask the authors' identities for reviewers (double masked), although masking is difficult to maintain. Peer review is usually a gift of uncompensated time from scientists to whom time is a precious commodity. It is therefore important for editors to clearly define the responsibilities of these individuals to implement processes that streamline the peer review as much as possible (see 2.3 for more on reviewer responsibilities).

Some **editor responsibilities to reviewers** are listed below.

- Assigning papers for review appropriate to the reviewers' areas of interest and expertise.
- Establishing a process for reviewers to ensure that they treat the manuscript as a confidential document and complete the review promptly.
- Informing reviewers that they are not allowed to make any use of the work described in the manuscript or take advantage of the knowledge they gained by reviewing it until it is published.
- Providing reviewers with written, explicit instructions on the journal's expectations for the scope, content, quality, and timeliness of their reviews to promote thoughtful, fair, constructive, and informative critique of the submitted work.
- Requesting that reviewers identify any potential conflicts of interest and asking that they recuse themselves if they cannot provide an unbiased review.
- Allowing reviewers appropriate time to complete their reviews.
- Requesting reviews at a frequency that does not overtax any one reviewer.
- Finding ways to recognize the contribution of reviewers, for example by publicly thanking them in the journal, providing letters that might be used in applications for academic promotion, offering professional education credits, or inviting them to serve on the editorial board of the journal.

Editors have the responsibility to inform and educate readers. Making clear and rational editorial decisions will ensure the best selection of content that contributes to the body of scientific knowledge.

Some **editor responsibilities to readers** are listed below.

- Evaluating all manuscripts considered for publication to make certain that each manuscript provides the evidence readers need to evaluate the authors' conclusions and that authors' conclusions reflect the evidence provided in the manuscript.
- Providing literature references and author contact information so that interested readers may pursue further discourse.



- Identifying individual and group authorship clearly and developing processes to ensure that authorship criteria are met to the editors' knowledge.
- Requiring all authors to review and accept responsibility for the content of the final draft of each paper or for those areas to which they have contributed; this may involve signatures of all authors or of only the corresponding author on behalf of all authors.
- Maintaining the journal's internal integrity (eg, correcting errors; clearly identifying and differentiating types of content such as reports of original data, opinion pieces such as editorials, letters to the editor, corrections/errata, retractions, supplemental data, and promotional material or advertising; identifying published material with proper references).
- Disclosing sources (eg, authorship, journal ownership, funding).
- Creating mechanisms to determine whether the journal is providing what readers need and want (eg, reader surveys).
- Disclosing all relevant potential conflicts of interest of those involved in considering a manuscript or affirming that none exist.
- Providing a mechanism for a further discussion on the scientific merits of a paper, such as by publishing letters to the editor, inviting commentaries, or soliciting other forms of public discourse.
- Explicitly stating journal policies regarding ethics, embargo, submission and publication fees, and accessibility of content (what is freely available vs what is under a subscription model).

Journals may be owned by professional societies or associations, foundations, universities, hospitals, research institutions, libraries, governmental organizations, or commercial publishers.

Some **editor responsibilities to journal owners** are listed below.

- Conducting peer review of submitted manuscripts and complying with the guidelines and procedures of the owner organization, including any terms specified in the contract with that organization.
- Making recommendations about improved evaluation and dissemination of scientific material.
- Operating the journal in a fiscally responsible manner.
- Adhering to the agreed-on mission, publication practices, and schedule.

Meeting all the obligations—which sometimes compete with one another—and handling the demands of other individuals and groups (such as the parent society, owners, publishers, funders and sponsors, authors, readers, advertisers, news media, and government agencies) require that the editor have editorial freedom, comprising both authority and autonomy.

### 2.1.1 Editorial Freedom

To establish and maintain high-quality journal content, an editor should, prior to accepting a position, receive an explicit, written statement from the journal's



owner that defines the editor's responsibilities and autonomy. Regardless of the scientific field, editors should be given full responsibility for editorial decisions on individual manuscripts (see 2.5). The editor's right to editorial freedom may be supported by the following and should be agreed on by both editor and journal owner/publisher:

- A journal mission statement.
- Written editorial priorities, objectives, and measures of success.
- Written editorial policies.
- A written job description, specifically detailing components of editorial freedom. Degree of control regarding editorial content, acceptance and publication, and advertising content should be specified. A sample job description can be found in the Appendix.
- An editorial board, including associate, assistant, and topic editors, that is nominated or appointed by and reports to the editor.
- Sufficient support from the parent society, publisher, owner, or other journal sponsors in both funding and staff to carry out the journal's stated mission.
- A mechanism for regular and objective evaluation of editor performance by the publisher or sponsoring organization based on predetermined and agreed-on measures of success.
- Direct lines of communication with the publisher, owner, and any publication oversight body.
- A mechanism to prevent inappropriate influence on the editor by others and to handle conflicts in an objective and transparent manner with the goal of conflict resolution and maintenance of trust.

### 2.1.2 Confidentiality

Editors and the publication staff should keep all information about a submitted manuscript confidential and limited to those involved in the evaluation, review, and publication processes. To eliminate the potential to influence editorial decisions, many journals have policies not to release content to the publication's sales team until it has been accepted or published. Journals should have a mechanism to safely store, archive, and/or destroy paper and electronic manuscript review files and related content. Confidential information should not be used for editors' own purposes, and editors should take reasonable steps to ensure that such information is not used inappropriately for the advantage of others. In cases of breach of confidentiality by those involved in the peer-review process, editors should contact the involved parties and follow up until satisfactory resolution is achieved.

Generally, editors of journals with embargo policies should enforce them to ensure that publication content remains confidential until the embargo release date, unless the editor is authorized by the copyright owner or required by law to disclose that information. The copyright owner is often the journal owner—



usually the society, publisher, or the author. There are 2 general exceptions under which an editor may release manuscript content to others not involved in consideration of the manuscript prior to publication: (1) to an author if a commentary or editorial is being solicited to highlight the manuscript, and (2) to the public when research findings have a major health or societal impact (a rare event). In the latter case, journals often prefer to coordinate release of the peer-reviewed study findings with announcements to the public so that details are clearly presented and widely disseminated. This type of content is often made freely available online prior to print. A good summary of the importance of releasing information to the public and honoring embargoes is described in an editorial about *JAMA*'s plans to coordinate with media to release a report from the National Heart, Lung, and Blood Institute Women's Health Initiative about the use of estrogen-plus-progestin hormone therapy and the consequences of the subsequent embargo break (<http://jama.ama-assn.org/cgi/content/full/288/6/748>) (see 2.6).

### 2.1.3 Conflicts of Interest

Conflicts of interest in publishing can be defined as conditions in which an individual holds conflicting or competing interests that could bias editorial decisions. Conflicts of interest may be only potential or perceived, or they may be factual. Personal, political, financial, academic, or religious considerations can affect objectivity in numerous ways.

Editors should set and regularly monitor a conflict-of-interest policy for editors, reviewers, editorial board members, editorial staff, and authors. These policies should be published in the journal with the date of their adoption or publication and made easily accessible to all readers by a parallel online publication (usually as part of the Instructions for Authors). Editors should strive for fairness and impartiality in their policies and enforcement. The challenge for editors is to recognize the potential for biases arising from conflicts of interest in the publishing process and to take appropriate action when biases are likely. Some specific types of conflict of interest are mentioned below.

- **Personal conflicts.** Editors should avoid making decisions on manuscripts that conflict with their own interest, such as those submitted from their department or by research collaborators or competitors or those addressing an issue in which they stand to gain financially (eg, holding stock in a company whose product is discussed in the article). If they may have a perceived or possible conflict of interest, editors should delegate handling of any decision to other editors. Also, editors should only submit their own manuscripts to the journal if full masking of the process can be ensured (eg, anonymity of the peer reviewers, lack of access to records of their own manuscript). Editorials are an exception to this rule.



- **Financial conflicts.** The most evident type of potential conflict of financial interest arises when an individual or organization may benefit financially from a decision to publish or to reject. Financial conflicts may include salary, consulting fees, research grants from a company with an interest in the results, honoraria, stock or equity interests, and intellectual property rights (patents, royalties, and copyrights). Some examples of potential direct and indirect financial conflicts of interest that should be avoided are given below.

**Direct:** An editor, author, or reviewer is reporting or considering a study involving a specific commercial product while he or she holds equity positions or stock options in the company making the product and thus has the potential to realize direct financial gain if the assessment is favorable.

**Direct:** A reviewer gains key knowledge from evaluating a competing research team's work, and uses it prior to the publication of the work, but does not cite it in his/her own patent application.

**Indirect:** An individual involved in the publication process is employed by an organization that would obtain some advantage from a favorable product-related publication or may receive compensation if a product does well as a result of a favorable report published in the journal.

**Indirect:** When an investigator studies the product of a commercial enterprise from which the investigator has received monies previously (eg, consulting fees, honoraria, speaking fees), the situation differs slightly. In such case, there is no direct relationship between the evaluation and a personal gain the investigator may anticipate. Nevertheless, previously received payments could conceivably influence the researcher's opinion and must therefore be regarded as a potential conflict of interest that should be disclosed.

**Indirect:** An author is being considered for a research grant and publication of an article favorable to the company reviewing the grant may influence the award.

- **Non-financial conflicts.** Other, non-financial conflicts of interest should also be avoided or disclosed. Some of these include personal, political, academic, and religious conflicts. Examples are listed below.
  - A reviewer evaluating a manuscript reporting research results similar to what he or she is preparing to submit for publication might be tempted to delay the review until his or her manuscript is accepted; or the reviewer may be unduly influenced by the concepts or hypotheses in his or her ongoing and unpublished research.
  - A reviewer with strong feelings on a controversial topic might be partial to or biased against a manuscript on the topic and want to publish or reject it regardless of scientific merit.



- An author of an editorial commenting on the importance of a research article may minimize positive findings if he or she has been a consultant to a company selling competing products.
- An editor chairing a department might struggle to reach an objective decision about a manuscript submitted by a member of his or her faculty because of his or her commitment to the academic advancement of those researchers.

#### 2.1.4 Conflict of Interest Disclosure

Journals should require disclosure of all conflicts of interest from everyone involved in the publication process: editors, reviewers, editorial board members, editorial staff, and authors. The intent of disclosure is to allow others to make an informed decision about the existence and impact of potential conflicts of interest or bias, including the necessity for recusal or disqualification under extraordinary circumstances. Editors are better equipped to make informed decisions on potential biases if they have full knowledge of all the circumstances, and readers and reviewers have more information to interpret the work when there is a public disclosure. However, some argue that mandatory disclosure of actual or perceived conflicts does not allow a manuscript to be judged solely on its scientific merits and may introduce prejudice. Under what circumstances a disclosure is needed and how it is handled varies among journals.

- **Author disclosures.** Some editors and journals require authors to identify the organizations that provided support for their research and describe the role played by these organizations in the study and in the analysis of the results. Authors may also be required to disclose all personal, financial, and other relationships they may have with the manufacturer of any product mentioned in the manuscript or with the manufacturers of competing products. For example, some journals do not permit consideration of manuscripts describing research involving a commercial product when the research was supported financially by a commercial organization involved in the manufacturing or sale of that product. Others will not permit editorials or review articles to be authored by individuals with potential conflicts of financial interest, feeling that these pieces rely especially heavily on interpretation and objectivity. Many journals follow the International Committee of Medical Journal Editors (ICMJE) recommendation to keep disclosed conflicts of interest confidential during the peer review process. This allows the editor to consider the potential conflicts after the scientific merit is assessed. Those journals that request and publish specific conflict-of-interest information are more likely to avoid inconsistent handling but may unnecessarily use editorial space for this purpose. While some journals ask that all potential financial conflicts be provided, others ask authors to identify only if they exceed a certain monetary amount. For example, the journal *Neurology*





states that the corresponding author must obtain the signed Author Disclosure Form <http://www.neurology.org/misc/AuthorDiscl.pdf> from all co-authors and reveal his or her own to co-authors; the journal keeps this information on file for 5 years after the date of submission. It further states: “Corresponding authors are also responsible for disclosing any co-author’(s)’ potential or real, financial or non-financial conflicts of interest in the manuscript in a ‘Disclosure’ section on the title page of the submitted manuscript and in writing to the Editor-in-Chief of *Neurology*.” The Disclosure Form specifically asks authors if more than \$10,000/year was received from the study’s corporate sponsors for (1) anything not reported in the articles, (2) honoraria during the study, (3) expert testimony on the subject of the article, (4) royalties for patents related to the topic of the article, and (5) whether the author has an equity or ownership interest in the sponsoring organization. In addition, if the article is accepted, the corresponding author is required to ensure that any disclosure appears on the page proofs. The ICMJE states: “Editors should publish this information if they believe it is important in judging the manuscript” (<http://www.icmje.org/index.html#conflicts>). This approach gives the editor the discretion to decide if the potential conflict is significant enough to reveal. Examples of some disclosure forms and actual disclosures are shown in the following links from the *Annals of Internal Medicine* ([http://www.annals.org/shared/author\\_info.shtml#conflictinterest](http://www.annals.org/shared/author_info.shtml#conflictinterest)) and the American Chemical Society ([https://paragon.acs.org/paragon/ShowDocServlet?contentId5paragon/menu\\_content/newtothissite/eg\\_ethic2000.pdf](https://paragon.acs.org/paragon/ShowDocServlet?contentId5paragon/menu_content/newtothissite/eg_ethic2000.pdf)). In general, editors should err on the side of too much disclosure.

- **Reviewer disclosures.** Some journals have established policies that require reviewers to reveal any potential personal or financial conflicts of interest with respect to the authors or content of manuscripts they are asked to review, or to affirm that they have no conflicts. In most instances when such conflicts exist, editors request that reviewers decline to comment on the manuscript. However, if a reviewer is a colleague of the author but believes that he or she can provide an objective review, the editor may allow the practice. Many journals use the same form for conflict of interest disclosures for reviewers as for authors, because the potential pitfalls are very similar.

### 2.1.5 Editorial Board Participation

The editor-in-chief or principal editor should define the terms and roles of the editors and editorial board members who are appointed by and report to him or her. As mentioned above, the editor-in-chief should require disclosure of any conflicts of interest. Some journals ask potential editors to identify service on other publication boards and may consider inappropriate an editor’s role in the editorial and financial decisions of a competing publication.





The editor-in-chief or principal editor should ensure that the journal's editors and board are identified in the journal masthead; receive the necessary training and oversight to adequately perform editorial functions; and actively participate in their responsibilities, such as assigning reviewers or reviewing manuscripts and advising on policy considerations.

#### 2.1.6 Timeliness of the Publication Process

Editors are responsible for monitoring the turnaround times for every publishing stage from manuscript receipt to publication or rejection. Processing data and evaluating trends can help editors scrutinize acceptance and rejection rates of specific types of manuscripts, manage the inventory/backlog of accepted manuscripts, track reviewers' and editors' performance, and assess staffing needs.

Some journals publish annual editorial audits, which include the total number of manuscripts submitted, acceptance rates of solicited and unsolicited manuscripts, and the average manuscript turnaround time. (An example can be found at: <http://www.conbio.org/Publications/Newsletter/Archives/1997-8-August/aug97008.cfm#A14>.) Many journals follow the practice of listing the dates of manuscript receipt and acceptance as part of the published article. This information helps answer questions from readers and potential authors about how long it will take to see their manuscript in print. The editor's responsibility for timeliness extends to providing prompt responses and decisions for all journal-related activities, including responses to authors' queries. Many journals provide an e-mail address or an online feedback form to facilitate communication with authors and readers.

#### 2.1.7 Errata, Retractions, and Expressions of Concern

Editors have a responsibility to maintain the integrity of the literature by publishing errata or corrections identifying anything of significance, retractions, and expressions of concern as quickly as possible (see 3.5). When appropriate, they should provide a forum (eg, letters to the editors) for offering responsible alternative opinions.

Errors in published articles require a published correction or erratum. These corrections should be made in such a way that secondary publication services, such as PubMed, will identify them and associate them with the original publication. Many online journals provide a direct link between the original article and the correction published later.

Editors should monitor the number and types of errors that appear in their journals. This review can be done simultaneously with the evaluation of other journal statistics. Editors should take corrective measures when there is evidence of an increase in preventable errors.



### 2.1.8 Addressing Authorship Disputes

Editors are responsible for promoting the integrity of the literature and fostering good publication practices. Journals should develop and define authorship or contributorship criteria to minimize confusion about expectations. (Authorship is more fully addressed in section 2.2.) Despite current common practice to make authorship or contributorship transparent, authorship disputes continue to persist. Examples include the “honorary” listing of a person who does not meet authorship criteria, submission of a manuscript without the knowledge or consent of an author/contributor, misrepresentation of a contribution, and an ordering of the byline that indicates a greater level of participation in the research than is warranted. A journal’s Instructions for Authors should define the criteria for authorship or contributorship, but policies should also be established to mediate authorship disputes. Authorship abuses may be driven by some factors that are beyond the role of the editor (tenure decisions, funding, awards). Editors, however, should collaborate with research institutions and other organizations to determine why these improprieties exist and to work toward solutions.

### 2.1.9 Appealing Decisions and Reconsideration of Rejected Manuscripts

Despite editors’ best efforts to solicit fair and unbiased reviews, disputes may still arise about editorial decisions. Editors should have a policy in place to help resolve these issues.

- Determine whether the decision was clearly explained to the author or whether the decision may have been based on wrong or questionable information, for example, on an incorrect reading of the manuscript or on bad advice from a reviewer.
- Reconsider rejected manuscripts if the author provides good reasons why the decision may have been wrong and is willing to revise the manuscript in response to the valid comments of the reviewers and editors. Many journals allow authors to write a rebuttal letter explaining why their manuscript should be reevaluated.
- Encourage resubmission of manuscripts that are potentially acceptable but were rejected because major revision or additional data were required, explaining precisely what is needed to make the manuscript acceptable.

### 2.1.10 Addressing Allegations or Findings of Misconduct (see 3.1 through 3.6)

Concerns about possible scientific misconduct are usually expressed first to the editors of a journal about a manuscript that is under consideration or has already been published. Every journal should develop a consistent policy to encourage the reporting of indications of misconduct, for evaluating the allegations, and for handling the findings. Journals should include a general statement in their Instructions for Authors that allegations of misconduct will be



pursued. Although the editor is not solely responsible for monitoring possible failures to meet legal or ethical research and publication standards, it is within his or her responsibilities to create and enforce policies that encourage good publication practices. When allegations and/or findings of misconduct are presented, the editor will be faced with some level of responsibility for investigating, judging, and/or penalizing the author for these lapses. The Council of Science Editors recommends that each journal articulate a specific policy on the editor's responsibility for notifying an author's institution of failure to comply with the journal's ethical standards. Additionally, the editor and the publisher have a responsibility to inform readers and secondary services of work formally proven to be plagiarized, fabricated, or falsified.

*(Authorship: Diane Scott-Lichter and Deborah Polly took the lead in writing this section of the white paper on behalf of the CSE Policy Committee. Members of the Policy Committee and the CSE Board of Directors reviewed and commented on it. This section was formally approved by the CSE Board of Directors on September 13, 2006.)*

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## APPENDIX

### Sample Job Description for an Editor

#### EDITOR-IN-CHIEF

Reports to journal's Publications Committee and owner's Board of Directors. Makes recommendations pertaining to improved dissemination of scientific material. Oversees journal's publications department staff in regard to the journal.

#### A. DUTIES

1. Possess a general scientific knowledge of the fields covered in the journal and be skilled in the arts of writing, editing, critical assessment, negotiation, and diplomacy.
2. Publish original, important, well-documented, peer-reviewed articles on a diverse range of scientific topics of interest to the readership.
3. Establish the policies for:
  - Submission of manuscripts and criteria for authorship/contributorship
  - Processes for peer review, evaluation of decisions regarding publication, and methods for reconsideration of rejected manuscripts
  - Identification and selection of theme issues and supplements
  - Conflict of interest and disclosure
  - Handling allegations and findings of scientific misbehavior and misconduct.
4. Communicate publication guidelines and policies (eg, Instructions to authors, Instructions to Reviewers, Ethical Guidelines, Editorial Board reports, Editorials).
5. Provide the journal owner, publications oversight committee, and/or editorial board with reports, as requested, on the journal's activities.
6. Preside at annual meetings of the editorial board and the executive committees.



7. Receive, review, and act on complaints from those involved in the publication process.
8. Review and approve the journal's yearly budget, as proposed by the managing editor, for approval by the journal's management committee.
9. Represent the editorial board in negotiations with the journal's publisher.

## **B. EDITORIAL FREEDOM**

The editor-in-chief will have complete authority for determining the editorial content within the defined scope of the journal and participate in the development of the advertising policy.

## **C. TERM OF APPOINTMENT**

1. The individual elected as editor-in-chief is expected to serve in that position for [a defined number of] years.
2. If a person serving as editor-in-chief is unable to complete the current term, [number] months' notice should be provided. The editor-in-chief may recommend a potential successors to the Society.

## **2.2 Authorship**

Trust is among the fundamental bases on which scientific communication rests: trust that the authors have fairly and accurately reported their findings and disclosed all pertinent commercial and professional relationships that could bias those findings, and trust that editors have exercised sufficient diligence and skepticism to ensure accurate reporting and disclosure by authors. This section focuses on principles to which authors should conform to ensure that this trust is not misplaced.

### **2.2.1 Authorship and Contributorship Models**

In 1985, the International Committee of Medical Journal Editors (ICMJE) published criteria within the Uniform Requirements for Manuscripts Submitted to Biomedical Journals that defined authorship. The current ICMJE statement on authorship (<http://www.icmje.org/#author>) reads:

- Authorship credit should be based on 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.
- When a large, multi-center group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship defined above and editors will ask these individuals to complete journal-specific author



and conflict of interest disclosure forms. When submitting a group author manuscript, the corresponding author should clearly indicate the preferred citation and should clearly identify all individual authors as well as the group name. Journals will generally list other members of the group in the acknowledgments. The National Library of Medicine indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript.

- Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.<sup>1</sup>

In the 1990s, this model came under scrutiny, in part because the number of people involved in running clinical trials increased and in part because authors failed to make adequate disclosures.<sup>2,3</sup> The perceived inadequacies in the ICMJE model led some to suggest a complementary model that departed from the more traditional concepts of authorship, in the hope that editors would be better able to elicit actual contributions from authors and to convey a more accurate sense of each author's responsibility for the study.<sup>2</sup>

This model of "contributorship" has been adopted by a number of major biomedical journals.<sup>4</sup> The general aim of contributorship disclosure is to have authors describe, based on a contributor taxonomy created by journal editors, exactly what each author did in the process of designing the study, such as accumulating funding for the study; recruiting subjects; coordinating, collecting, and analyzing the data; writing and revising the study; and so forth.<sup>3</sup> Under this model, authors are also expected to designate their functional role within the group (eg, principal investigator, coinvestigator, statistician, contributing author).<sup>3</sup> It is argued that this additional layer of disclosure contributes to greater transparency on the behalf of authors.<sup>4</sup> ICJME has pointed out that contributorship is not designed to replace the ICJME criteria for defining "quantity and quality" of authorship but to complement it.<sup>1</sup>

1. International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Available at: <http://www.icmje.org/#author>. Accessed May 2, 2006.
2. Rennie D, Yank V, Emmanuel L. When authorship fails: a proposal to make contributors accountable. *JAMA*. 1997;278:579-585.
3. Yank V, Rennie D. Disclosure of researcher contributions: a study of original research articles in *The Lancet*. *Ann Intern Med*. 1999;130:661-670.
4. Report to the Council of Biology Editors From the Task Force on Authorship. Who's the author? problems with biomedical authorship, and some possible solutions. *Science Editor*. 2000;23: 111-119.



### 2.2.2 Aims of Authorship and Contributorship Models

The rationale behind the ICMJE authorship criteria and contributorship disclosures is to acquire an affirmation from each author and/or contributor on which editors can rely, to disclose publicly to readers what each author did,<sup>4</sup> and to gain from authors what Jerome Kassirer has described as “public responsibility for [article] content.”<sup>5</sup>

What authorship problems are editors specifically trying to identify and address? A range of undesirable types of authorship have been described, including guest authorship, honorary or gift authorship, and ghost authorship.<sup>4</sup>

**Guest authorship.** Guest authorship has been defined as authorship based solely on an expectation that inclusion of a particular name will improve the chances that the study will be published or increase the perceived status of the publication. The “guest” author makes no discernible contribution to said study and so meets none of the criteria for authorship.

**Honorary or gift authorship.** Honorary or gift authorship has been defined as authorship based solely on the basis of a tenuous affiliation with a study. A salient example would be “authorship” based on one’s position as the head of a department at which the study took place.

**Ghost authorship.** Ghost authorship is defined as a failure to disclose a contribution that would meet ICMJE criteria for authorship. A common example of ghost authorship is undisclosed contributions of medical writers to the draft of a manuscript.

### 2.2.3 Authors’ Role

**Confidentiality.** The author-editor relationship is founded on confidentiality. All communication between an author and editor within the context of a specific manuscript is to be held in confidence. Authors should designate a specific contact for all communication about the manuscript throughout peer review and (if accepted) the publication process. Authors should observe journal policy on communication with external peer reviewers (the policy may vary depending on whether a journal uses masked or nonmasked peer review) and should observe journal policy on prepublication embargoes (see 2.6).

**Disclosure.** Authors have a responsibility to be forthright when complying with journal submission requirements. This entails disclosure about the originality of the content, a statement of an author’s actual contribution to the study, financial and conflict of interest disclosures (some journals also require statements on the regulatory status of any drugs or devices used in the study), and, if applicable, a statement of compliance with standards for human subjects research (Declaration of Helsinki [<http://www.wma.net/e/policy/b3.htm>]),

5. Kassirer JP. Authorship criteria. *Science*. 1995;268:785–786.





institutional review board approval, informed consent forms, and/or relevant National Institutes of Health forms [<http://ohsr.od.nih.gov/>]). Authors should expect editors to publish all relevant disclosures with their accepted manuscript.

**Originality.** The authors should provide a statement attesting to the originality of the study they have submitted for consideration. Originality is critical because many journals have limited space and editors may give a low priority to studies that, regardless of scientific accuracy and validity, do not advance the scientific enterprise. Some journals may ask authors to provide copies of reports on other studies (articles, manuscripts, abstracts) related to the study under consideration.

**Contributorship.** Some journals use a contributorship form, wherein authors attest to their specific contributions. Authors may expect that editors will publish these statements with their accepted manuscript. (Examples of contributorship forms can be found at: <http://archopht.ama-assn.org/misc/ophtauthorshipform.pdf> and <http://www.annals.org/shared/AuthorsForm.pdf>.)

**Financial and conflict of interest disclosures.** Many journals require authors to divulge sources of funding for the study under consideration. Authors should disclose all sources of funding (government, corporate, other) and any products or services (such as materials and equipment, statistical analysis, and scientific writing) provided by third parties in the course of doing the research and reporting the findings (medical writing, statistical analysis). Some journals stipulate that authors disclose financial relationship in dollar amounts and set specific dollar thresholds. Items to be disclosed include employment, consultancies, stock ownership, honoraria, expert testimony, patents, and so forth. (An example of a disclosure form can be found at: <http://authors.nejm.org/misc/disclosRev.pdf>.)

**Drug and device statements.** Some journals require authors to provide a statement on the regulatory status of any drugs or devices used in the study. (An example of a regulatory status statement can be found at: [http://www.elsevier.com/framework\\_products/promis\\_misc/623354dsca.pdf](http://www.elsevier.com/framework_products/promis_misc/623354dsca.pdf).)

**Human subjects research.** All journals should require formal affirmation that human subjects research on which a submission is based was approved by an institutional review board or complied with the Declaration of Helsinki and that the researchers conducted the study according to acceptable research standards, including obtaining informed consent. Some categories of manuscript submissions may not require institutional review board approval.

**Animal research.** All journals should require formal affirmation that any research involving animals was approved by an animal research committee and was conducted according to the approved protocol as applies to animal care and experimentation.



#### 2.2.4 Copyright Assignment

In medical publishing, authors are usually expected to assign copyright to the journal publishing their study. In other disciplines (eg, legal publishing) copyright assignment may not be the standard. Assignment of copyright is a legal document in which the authors assign certain rights to the publisher. It is also assumed that the content in question is original and not otherwise under copyright elsewhere (in whole or in part). Authors should ensure that the study under consideration is original and does not contain plagiarized content. In addition, authors should avoid self-plagiarism—that is, reproducing verbatim content from their other publications. Some journal editors may not be willing to consider submissions containing content the authors have published elsewhere because it can be construed as a violation of copyright and may be an indicator that the study only marginally contributes to the literature.

#### 2.2.5 Order of Authorship

The order of authors in the byline is a decision of the authors or study group. Much has been written about the meaning of each place in the byline listing, particularly among the first 6 slots.<sup>6</sup> Authors should not expect editors to become embroiled in disputes among authors over name placement in the byline. Some journals specify how many authors they will accept in the author byline. The number can range between 3 and 25. Authors of biomedical papers may want to consider how the National Library of Medicine lists authors.

#### 2.2.6 Anonymous Authorship

In rare cases, journal editors may publish anonymous content. Such a practice should be discouraged, but it may be necessary if the author can make a credible claim that attaching his/her name to the document could cause serious hardship (eg, threat to personal safety or loss of employment). Because authorship should be transparent, it is not appropriate to allow authors to use pseudonyms for scientific reports. It has been suggested that pseudonyms are acceptable if the article in question is fiction. None of these rare cases obviates the editors' responsibility to collect all relevant disclosures and copyright documents.<sup>6</sup>

#### 2.2.7 Group Authorship

Group authorship ([http://www.councilofscienceeditors.org/publications/group\\_authorship.pdf](http://www.councilofscienceeditors.org/publications/group_authorship.pdf)), which has become increasingly common in biomedical publishing, occurs when, for example, a group of researchers has collaborated

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6. *American Medical Association Manual of Style: A Guide for Authors and Editors*. 9th ed. Baltimore, Md: Lippincott Williams and Wilkins; 1997:89-95.



on a multicenter trial, a consensus document, or an expert panel. Because it can be inaccurate and impossible to list all collaborators (because some would not meet basic ICJME authorship criteria and byline space may preclude such a listing), authors need to think about how to communicate credit and responsibility for content. The editors of *JAMA* have outlined 2 group authorship models<sup>6</sup>:

- Authorship in which each person in the group meets authorship criteria, in which case the group is listed as the author, with the caveat that editors may require at least 1 coauthor to assume the role of content guarantor.
- Authorship in which a select subgroup of the whole is listed in the byline on behalf of the whole.

#### 2.2.8 Deceased Authors

For cases in which a coauthor dies or is incapacitated during the writing, submission, or peer review process, coauthors should obtain disclosure and copyright documentation from a familial or legal proxy.<sup>6</sup>

#### 2.2.9 Acknowledgments

Authors are expected to provide a list of people whose contribution to a study did not qualify them for authorship or, because of journal policy on the number of authors in the author byline, cannot fit in the author byline. Authors should have each person listed in the acknowledgment sign a disclosure form or at least should obtain a signed statement from the people in the group acknowledging that they know their names will appear in the published document.

#### 2.2.10 Multiple Submissions

This practice is acceptable in some other disciplines (eg, legal publishing). In the biomedical sciences, it is not acceptable for authors to submit the report of a study to several journals at the same time, including a manuscript undergoing peer review that has not been formally rejected by the original journal to which the manuscript was submitted. If authors wish to submit the manuscript to another journal, all authors should formally withdraw the manuscript to avoid self-plagiarism misconduct (see 3.1.3). Authors who violate this standard may find that editors reject their papers as a violation of policy.

If authors want to submit their article to another journal while it is already under consideration elsewhere, then they must send formal notification to the editor of the journal with whom it is under consideration requesting that their study be withdrawn from further consideration. All coauthors must agree to the request for withdrawal and this agreement must be made clear to the editor of the journal with which the study is under consideration. Authors should request formal acknowledgment from the journal to the effect that the editors understand the study has been withdrawn from future consideration. On receipt of notification from the journal acknowledging the withdrawal, the authors may submit their study elsewhere. They should retain a copy of the notification.



### 2.2.11 Registration of Clinical Trials

In 2004, ICJME adopted a policy on registration of prospective interventional clinical trials ([http://www.icmje.org/clin\\_trialup.htm](http://www.icmje.org/clin_trialup.htm)). This policy requires, as a condition of submission, that authors or trial sponsors register their trials, prior to subject enrollment, with approved trial registries. Authors should take into consideration whether the journals to which they may want to submit their study have adopted this policy.

### 2.2.12 Editors' Role

**Explanation and enforcement of authorship disclosure.** It is the editors' responsibility to establish the authorship criteria by which their journals will abide. The standard by which many biomedical journals operate is that of ICMJE. It is the editors' responsibility to publish their authorship criteria (in print and/or electronic media) and then to enforce these standards by collecting relevant documentation from authors. Collection can take place either at manuscript submission or at some point during the peer review process, preferably prior to any commitment to accept and publish a study. An observational study by Bates et al<sup>7</sup> suggests that, among 3 highly regarded biomedical publications, the effectiveness of authorship and contributorship policies varies.

**Authorship forms.** Editors usually require authors to complete and sign documents that confer copyright, attest to compliance with accepted standards in human subjects research (if applicable), attest to the originality of the study under consideration, attest to having participated as an author and reviewed the final submission, and disclose study funding and any conflicts of interest relevant to the study in question. It has been pointed out that authors are not consistent in actually having read these forms and disclosures.<sup>4</sup> Some journals, rather than accept a simple signature as evidence of compliance, have used a check-box method to draw authors' attention to portions of the documents and disclosures to which they are attesting.

**Compliance with requests from funding agencies for access to funded content.** Some funding bodies have asked (or in some cases required) authors to make the findings of research funded by their organizations accessible to the public. In 2005, the US National Institutes of Health (NIH) suggested that authors receiving grants from NIH send an electronic file of their manuscript at acceptance to PubMed Central. NIH policy stipulates that authors inform PubMed Central when, during a 12-month window after acceptance, PubMed Central can release the content. Editors of journals that accept biomedical papers should give authors guidance on how they would like authors to instruct PubMed Central; editors should also consider altering their journals' copyright assignment forms if

7. Bates T, Anic A, Marusic M, Marusic A. Authorship criteria and disclosure of contributions. *JAMA*. 2004;292:86-88.



they do not accommodate these requests. The Wellcome Trust (in the United Kingdom) mandates that authors deposit their manuscript in PubMed Central within 6 months of publication. The UK Research Councils has stated that after October 1, 2005, all published research with Research Council funding should be deposited in a “subject-based or institutional e-repository (subject to copyright or licensing agreements)” at or around the time of publication of the article.

*(Authorship: Michael Vasko took the lead in writing this section of the white paper on behalf of the CSE Policy Committee. Members of the Policy Committee and the CSE Board of Directors reviewed and commented on it. This section was formally approved by the CSE Board of Directors on September 13, 2006.)*

## Resources and Case Studies

- Committee on Publication Ethics. Guidelines on good publication and the code of conduct. Available at: <http://www.publicationethics.org.uk/guidelines>. Accessed May 1, 2006.
- Council of Science Editors. CSE recommendations for group-author articles in scientific journals and bibliometric databases. Available at: [http://www.councilofscienceeditors.org/publications/group\\_authorship.pdf](http://www.councilofscienceeditors.org/publications/group_authorship.pdf). Accessed May 2, 2006.
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- World Medical Association. Policy: World Medical Association Declaration of Helsinki. Ethical principles for medical research involving human subjects. October 9, 2004. Available at: <http://www.wma.net/e/policy/b3.htm>. Accessed April 30, 2006.

## 2.3 Reviewer Roles and Responsibilities

Peer review is an essential component of the conduct of science and its dissemination and remains the principal mechanism by which the quality of research is judged. Most funding decisions in science and the academic advancement of scientists are based on peer-reviewed publications.

Because the number of scientific articles published each year continues to grow, the peer-review process, together with the quality of the editorial board, is cited as the primary influence on a journal’s reputation, impact factor, and standing in the field.

Scientific journals publishing peer-reviewed articles depend heavily on the scientific referees or reviewers who, in most cases, volunteer their time and expertise to participate in the peer-review process. In most circumstances, at least 2 reviewers are solicited to evaluate a manuscript; some journals request 3 reviews. In



cases of controversy or strong disagreement regarding the merits of the work, an additional review might be solicited or one of the journal's editors might give an evaluation. Also, more than 3 reviewers are sometimes used if reviewers from several fields appear to be needed to obtain a thorough evaluation of a paper.

This important process requires both fairness in judgment and expertise in the field. Peer reviewers also have significant responsibilities toward authors, editors, and readers.

Some **peer reviewer responsibilities to authors** include:

- Providing written unbiased feedback in a timely manner on the scholarly merits and the scientific value of the work, together with a documented basis for the reviewer's opinion.
- Indicating whether the writing is clear, concise, and relevant and rating the work's composition, scientific accuracy, originality, and interest to readers.
- Avoiding personal comments or criticism.
- Refraining from direct author contact without the editor's permission.

Some **peer reviewer responsibilities to editors** include:

- Notifying editor immediately if unable to review in a timely manner and providing the names of potential other reviewers.
- Determining scientific merit, originality, and scope of the work; indicating ways to improve it; and recommending acceptance or rejection while using a rating scale.
- Noting any ethical concerns, such as substantial similarity between the reviewed manuscript and any published paper or any manuscript concurrently submitted to another journal. Any violation of accepted norms of ethical treatment of animal or human subjects should also be pointed out.
- Alerting the editor about any potential personal or financial conflict of interest and declining to review when a possibility of a conflict exists (see 2.3.2).

Some **peer reviewer responsibilities to readers** include:

- Ensuring that the published articles adhere to the journal's standards.
- Protecting readers from incorrect or flawed research or studies that cannot be validated by others.
- Being alert to any failure to cite relevant work by other scientists.

### 2.3.1 Reviewer Selection

Editors, frequently with the assistance of electronic databases of reviewers kept by their journal's offices, choose reviewers whose expertise most closely matches the manuscript's topic and invite them to review the paper. The editors also consider the number of manuscripts sent to a reviewer so as not to overburden any one expert.

Frequently the reviewer selection process and the journal's internal policies address the issue of potential bias by eliminating reviewers from the same





institution as that of the author(s) and by asking the reviewer to disclose any potential conflict of interest. Reviewers might also be asked to disclose to the editor any personal or professional connection to the author(s) and decline the assignment if they feel unqualified to do the review or cannot review in a timely manner. This “bias screening” at the point of reviewer selection may be incorporated into an online submission system or posted on the journal site as a policy.

### 2.3.2 Ethical Responsibilities of Reviewers

**Confidentiality.** Material under review should not be shared or discussed with anyone outside the designated review process unless necessary and approved by the editor. Material submitted for peer review is a privileged communication that should be treated in confidence, taking care to guard the author’s identity and work. Reviewers should not retain copies of submitted manuscripts and should not use the knowledge of their content for any purpose unrelated to the peer-review process.

Although it is expected that the editor and/or reviewers will have access to the material submitted, authors have a reasonable expectation that the review process will remain strictly confidential. If a reviewer is unsure about the policies for enlisting the help of others in the review process, he or she should ask the editor.

**Constructive critique.** Reviewer comments should acknowledge positive aspects of the material under review, identify negative aspects constructively, and indicate the improvements needed. Anything less leaves the author with no insight into the deficiencies in the submitted work. A reviewer should explain and support his or her judgment adequately so that editors and authors may understand the basis of the comments. Any statement that an observation or argument has been previously reported must be accompanied by a relevant citation. Knowledge of duplicate publication should also be shared.

The purpose of peer review is not to demonstrate the reviewer’s proficiency in identifying flaws. Reviewers have the responsibility to identify strengths and provide constructive comments to help the author resolve weaknesses in the work. A reviewer should respect the intellectual independence of the author.

Although reviews are confidential, all comments should be courteous and capable of withstanding public scrutiny.

**Competence.** Reviewers who realize that their expertise is limited have a responsibility to make their degree of competence clear to the editor. Although a reviewer may not be an expert in every aspect of the content, the assignment should be accepted only if he or she has adequate expertise to provide an authoritative assessment. A reviewer without the requisite expertise is at risk of recommending acceptance of a submission with substantial defi-





ciencies or rejection of a meritorious paper. In such cases, a reviewer should decline the review.

**Impartiality and integrity.** Reviewer comments and conclusions should be based on an objective and impartial consideration of the facts, exclusive of personal or professional bias. All comments by reviewers should be based solely on the paper's scientific merit, originality, and quality of writing as well as on the relevance to the journal's scope and mission, without regard to race, ethnic origin, sex, religion, or citizenship of the authors.

A reviewer should not take scientific, financial, personal, or other advantage of material available through the privileged communication of peer review, and every effort should be made to avoid even the appearance of taking advantage of information obtained through the review process. Potential reviewers who are concerned that they have a substantial conflict of interest should decline the request to review or discuss their concerns with the editor.

**Disclosure of conflict of interest.** To the extent possible, the system of review should be designed to minimize actual or perceived bias on the reviewer's part. If reviewers have any interest that might interfere with an objective review, they should either decline a role as reviewer or disclose the conflict of interest to the editor and ask how best to address it. Some journals require reviewers to sign disclosure forms that are similar to those signed by authors.

**Timeliness and responsiveness.** Reviewers are responsible for acting promptly, adhering to the instructions for completing a review, and submitting it in a timely manner. Failure to do so undermines the review process. Every effort should be made to complete the review in the time requested. If it is not possible to meet the deadline for the review, then the reviewer should promptly decline to perform the review or should inquire whether some accommodation can be made to resolve the problem.

### 2.3.3 Examples of Reviewer Impropriety

- Misrepresenting facts in a review.
- Unreasonably delaying the review process.
- Unfairly criticizing a competitor's work.
- Breaching the confidentiality of the review.
- Proposing changes that appear to support the reviewer's own work or hypotheses.
- Making use of confidential information to achieve personal or professional gain.
- Using ideas or text from a manuscript under review.
- Including personal or ad hominem criticism of the author(s).
- Failing to disclose a conflict of interest that would have excluded the reviewer from the process.



#### 2.3.4. Using Anonymous Reviewers: Critique of the Process

For many scientific journals, the peer review is performed as a “partially masked” system where the names of the reviewers are unknown to the authors, but the names of the authors are known to reviewers and editors. Other journals use a double-masked system, where the reviewers do not know the identity of the authors or their affiliation.

There is an ongoing discussion on whether the popular model of the partially masked peer review is optimal, and some journals and editors<sup>8</sup> propose a fully open system in which all participants know each other’s identities. There are strong arguments for and against each model, but most journal editors consider anonymity of the reviewer a norm that they are not willing to change.

The strongest criticism of the partially masked peer-review process has to do with the fact that, even when all precautions are taken, the process remains highly subjective and relies on reviewers who may take advantage of ideas they find in yet-unpublished manuscripts; show bias in favor or against a researcher, an institution, or an idea; be insufficiently qualified to provide an authoritative review; or abuse their position because they do not feel accountable.

The open peer-review concept (where all parties’ identities are fully disclosed) offers its own dilemmas, however. Knowledge of reviewers’ names could make them objects of animosity or vengeful behavior and consequently reviewers could become less critical and impartial, especially when judging their colleagues’ work. This can also occur with the partially masked system, particularly within small specialties where researchers can easily guess who reviewed the manuscript.

*(Authorship: Anna Trudget took the lead in writing this section of the white paper on behalf of the CSE Policy Committee. Members of the Policy Committee and the CSE Board of Directors reviewed and commented on it. This section was formally approved by the CSE Board of Directors on September 13, 2006.)*

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## 2.4 Sponsor Roles and Responsibilities

The role of sponsoring agencies (eg, pharmaceutical firms, contract research organizations, academic entities) in the publication of study results is defined primarily in 6 areas:

- Authorship/contributorship
- Process control (content, direction, and venue choice)
- Disclosure of funding sources and sponsor involvement
- Access to and provision of data
- Copyright
- Sponsor misconduct and/or unethical practices



Communication between the journal and its sponsor, just as between the journal and its authors, is key to ensuring that the sponsor's proper role is defined and fulfilled. For manuscripts that identify a sponsor, the publisher, at its discretion, may request the name and contact information for a corresponding sponsor agent to serve as a sponsor's representative. This representative may be a third party (ie, not directly employed by the sponsor but acting in an agent capacity).

#### 2.4.1 Authorship/Contributorship

Sponsors of a study and any subsequent manuscript(s) often include one or more employees or consultants as authors. These authors are bound to the authorship requirements set forth by the journal, often, for biomedical journals, based on the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for authorship (<http://www.icmje.org/>). In particular, it is required that all authors must make significant intellectual contributions to the manuscript. "Courtesy" authorships on behalf of sponsor executives are inappropriate. Authorship for sponsor representatives is welcomed as long as the individuals meet the requirements.

Ghost authorship is to be discouraged. The World Association of Medical Editors defines ghost authorship as existing when someone has made substantial contributions to writing a manuscript and the role is not mentioned in the manuscript itself (<http://www.wame.org/wamestmt.htm#ghost>). Additionally, we suggest that contributions to decision and analysis without attribution might also constitute ghost authorship. If a medical writer is used, sponsors should consult the ICMJE authorship requirements, the journal requirements, and the European Medical Writers Association guideline on the role of medical writers in developing peer-reviewed publications (see Resources and Case Studies section). Sponsors should realize that editors typically require corresponding authors to be forthright about all contributors and ensure that they comply with journal criteria for authorship. Alternatively, if a writer meets criteria for an acknowledgment, journals may ask authors to obtain a signed statement from all acknowledgees detailing the contribution that warranted inclusion in the acknowledgments. Journals may also ask for disclosures of conflicts of interest from acknowledgees.

#### 2.4.2 Process Control (Content, Direction, and Venue Choice)

Authors' independence from undue sponsorship influence is essential. In the course of executing usual authorship affidavits, editors and publishers may require authors to warrant that they submit the manuscript of their own free will, without undue influence from the sponsor. This affidavit may require authors to warrant that they agree with the interpretation of the results and the conclusion as stated in the manuscript. Whatever their relationship with the sponsor, it is important that authors ensure that the results in the submitted



paper are based solely on the scientific merit of the study (regardless of the outcome). Additionally, the authors should be free to submit the paper to the journal they consider most appropriate for the manuscript.

#### 2.4.3 Disclosure of Funding Sources and Sponsor Involvement

Sponsors should be transparent in disclosing financial or other in-kind support provided to authors and/or guest editors. Similarly, authors and/or guest editors must disclose all financial or in-kind support received from the sponsors and disclose current relationships with the funding source. The sponsor's relationship with the authors should be clearly stated in the conflict of interest disclosure signed by the authors (eg, employment, grants or other financial support, research materials supplied by the sponsor). Sponsors should realize that editors may also ask that specific roles (if any) of the sponsor in manuscript development be declared (eg, the role of sponsor in research design, data collection/analysis, decision to publish, and choice of journal). Or, if the sponsor took no such roles in the study, this should be stated (see the ICMJE authorship requirements for more details).

#### 2.4.4 Access to and Provision of Data

To protect the integrity of published results, all study investigators and manuscript authors should have access to the full data set their paper reports. Authors should have the right, regardless of sponsorship, to mine all the data for their publication. Editors and publishers may require sponsors to warrant that all authors of the submitted manuscript have full access to the data and results reported, and/or require that authors acknowledge that they have been granted full data access. If asked, sponsors of research should clearly outline policies or restrictions for sharing data and materials to investigators and journals, including requirements for providing information in repositories. Sponsors should be prepared to cooperate with journal requests to authors for data. Some journals may require registration of phase 3 clinical trials, and it is the sponsor's responsibility to register the clinical trial (see also the Council of Science Editors editorial policy statement: [http://www.councilscienceeditors.org/services/cse\\_editorial\\_policies.cfm#Paragraphnine](http://www.councilscienceeditors.org/services/cse_editorial_policies.cfm#Paragraphnine)). Sponsors and researchers should avoid entering into agreements that inhibit sharing of data and materials that support claims in the publication process. Authors should be able to remove their name from a manuscript if their access to data is compromised.

#### 2.4.5 Copyright

Sponsors must be aware of and comply with the copyright (or licensing) policies of journals that publish their results. Sponsors are not entitled to modify licensing and copyright agreements. Editors and publishers may require sponsors to acknowledge that all authors have signed copyright release or licensing forms. Resubmission of substantially similar results to another journal, under



the direction or influence of the sponsor, may require permission of the copyright holder. Sponsors should avoid duplicate and redundant publication of primary study results. Secondary publications resulting from a study should cite the primary publication and should be different enough to warrant a secondary publication.

#### 2.4.6 Sponsor Misconduct and/or Unethical Practices

Sponsor misconduct or unethical practices includes, but is not limited to:

- Undue influence on authors regarding interpretation of results and/or conclusions, as well as undue influences on what results to include and where to submit a manuscript.
- Withholding of data or materials from outside authors.
- Improper authorship or failure to report authorship.
- Failure to disclose financial or in-kind support.
- Undue influence on reviewers to ensure publication of results supporting a sponsor's product or device.

Any or all of these may be grounds for a journal correction or retraction if determined inappropriate by the editor after a complete and fair investigation (see part 3.)

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## 2.5 Relations Between Editors and Publishers, Sponsoring Societies, or Journal Owners

Scientific and editorial ethics are founded on integrity, competence, and a responsibility to protect the communal and public interest. Scientific editors strive to advance the reporting of science in ways that ensure the highest standards of reliability, accessibility, transparency, and integrity of the scientific enterprise and promote the broader ethical and communal interests of science in the public domain.





Editors should have total responsibility, authority, and accountability for the editorial content of the journal, an arrangement that is usually referred to as “editorial independence.” The journal should have a stated policy on editorial independence, and a disclaimer indicating that material published in the journal does not represent the opinion of the publisher, sponsoring society, or journal owner should be published regularly. Editors should resist any action that might compromise editorial independence. Editors must be free to authorize publication of peer-reviewed and other appropriate research reports, as well as society news, appropriate advertising, and other materials. The publisher, sponsoring society, or journal owner is usually responsible for financial and other management issues and business policies, but it should always recognize and accept the journal’s scientific integrity and objectivity and the editorial independence of the editor, and it should not interfere in the assessment, selection, or editing of journal articles. The relationship between the editor and the publisher, sponsoring society, or journal owner should be based on trust and respect.

Editors and publishers, sponsoring societies, or journal owners should have a signed contract to ensure proper editorial freedom and responsibility. The contract should identify the officers, committee, or other management group to whom the editor is primarily responsible. The publisher, sponsoring society, or journal owner should ensure that the editor has direct access to the highest management level and, preferably, reports to a governing body and not to an individual administrator. The contract should state the editor’s rights and duties and contain the editor’s job description, reporting responsibilities, and performance measurements. These should include statements of the scientific, editorial, and administrative expectations of all parties, the length of the contract, financial conditions including operating expenses and remuneration (if any), and terms for termination by either party. There should be a mechanism for resolving conflicts between the editor and the publisher, sponsoring society, or journal owner. A journal oversight committee for performance review and evaluation and for conflict resolution should be considered.

To maintain professional autonomy associated with publication of peer-reviewed reports, editors should not allow their editorial judgment to be influenced by political, commercial, or other considerations. Editors should be able to express views that might run counter to the positions, commercial aims, or strategic plans of the publisher, sponsoring society, or journal owner. Editors should have the right to review and refuse advertisements and advertising placement. Advertising considerations should not influence editorial decisions. The editor and the publisher, sponsoring society, or journal owner should confer about any political, commercial, or other incidents that could impair the scientific credibility of the publication and should agree to measures necessary to ensure that such incidents do not affect the decisions of the editor.





Editors should annually disclose any non-editorial, scientifically related activities in which they are engaged to the publisher, sponsoring society, or journal owner, regardless of whether the editor is a volunteer or employed on a part- or full-time basis.

Peer review and other publication assignments should be undertaken by qualified specialists as necessary. These specialists should disclose any conflicts of interest with the editor, submitting authors, publisher, sponsoring society, or journal owner. The journal should institute procedures that guard against potential conflicts involving the editor or the journal owner.

Editors and publishers, sponsoring societies, or journal owners should work together to ensure that services and products of contractors, vendors, and other commercial interests required for proper publication are selected on the basis of merit. Publishers, sponsoring societies, or journal owners should consider maintaining the necessary insurance to cover themselves and other key decision makers against legal action.

Editors should not disclose confidential information unless they are authorized by the source of that information, there are allegations of misconduct that require access to that confidential information for proper investigation (see 3.6), or they are required by law to do so. In the case of misconduct, if the editor determines that disclosure is warranted and appropriate, the allegations of misconduct should be made known to the publisher, sponsoring society, or journal owner. To maintain editorial independence, there should be agreement between the editor and the publisher, sponsoring society, or journal owner on the nature of editorial material, whether manuscripts, reviews, or minutes, that may rightly be viewed as confidential and thus unavailable to the journal owner.

The editor may be called on to assist the publisher, sponsoring society, or journal owner in the education and training of new editors.

*(Authorship: Stephen Morrissey took the lead in writing this section of the white paper on behalf of the CSE Policy Committee. Members of the Policy Committee and the CSE Board of Directors reviewed and commented on it. This section was formally approved by the CSE Board of Directors on September 13, 2006.)*

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## 2.6 Responsibilities to the Media

Journals work with media outlets to ensure that notable scientific advances are reported in the press. From a journal's point of view, media coverage of scientific articles has at least 3 purposes:

- Accurate media coverage of published science increases the likelihood that new scientific findings are understood by the public.
- Media coverage helps authors of scientific reports increase the impact of their research by reaching audiences beyond that of the journal alone.
- Media attention helps build a journal's brand recognition among scientific and general audiences.

To help the media responsibly cover science, journals should consider adopting some or all of the following practices:

- Routinely assess the public interest in reports scheduled for publication in the journal. Identify newsworthy articles in house or in conjunction with a media relations department, sponsoring society, or publisher (if applicable) and develop plans to highlight these articles in press materials.
- Prepare press materials in concise, everyday language that accurately presents the scientific research reported in the article. This can be done in conjunction with a media relations firm or the journal's society or publisher (if applicable). To help journalists assess the importance of the report, press materials should also provide background information and describe study limitations.
- In addition to press materials, journals should help the media prepare accurate reports by answering questions, supplying advance copies of the journal or article on request, and referring reporters to the appropriate experts. A 1-week advance notice of an upcoming publication (while still honoring the embargo date regarding official release) provides the media with ample time to prepare press material.

In the United States and some other countries, some journals release press materials and access to related articles during an embargo period. An embargo is an agreement or request that a news organization refrain from reporting information,



until a specified date and/or time, in exchange for advance access to the information. Not all journals use this system for information dissemination. The embargo period provides time for the media to develop stories before the scientific article is published. In general, a journal should adopt embargo policies that help as many members of the media as possible to accurately cover the science reported in their publication. However, some journals specify the type of journalists who warrant access to embargoed information. To help the media know when to expect press materials from a journal, all articles are embargoed for release until a specified date. The longer the embargo period, the more time journalists have to develop a story. A 3- to 5-day embargo period is reasonable. The full article should be available to the media on request. The embargo of the full issue can be removed the day the issue is released to the public (online or in print). If there is no embargo date established, the available date is the date of publication (online or in print). Embargo policies work on the honor system and there is little recourse for a journal when a journalist violates the terms of the embargo. However, violations should be brought to the attention of the news organizations. Members of the media who do not honor the embargo can be potentially denied access to embargoed material if violations persist.

Journals should inform authors of the intent to prepare press materials for their article. If the article has a corporate sponsor, the sponsor is expected to follow the media guidelines of the journal. If an author's organization is planning an independent press release or other media strategy, these activities should be coordinated with journal staff. Authors should contact the journal before speaking with the press to coordinate embargo periods, background information, and publication date.

Authors are encouraged to grant interviews with reporters or discuss other information related to their study provided the reporter agrees to honor the embargo in order to disseminate clear and accurate information regarding a manuscript. The embargo enables the reporter to have time to cultivate a well-thought-out story.

*(Authorship: John Ward and Jennifer Mahar took the lead in writing this section of the white paper on behalf of the CSE Policy Committee. Members of the Policy Committee and the CSE Board of Directors reviewed and commented on it. This section was formally approved by the CSE Board of Directors on September 13, 2006.)*

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## 3.0 IDENTIFYING RESEARCH MISCONDUCT AND GUIDELINES FOR ACTION

### 3.1 Description of Research Misconduct

Although no standard definition of research misconduct exists, and although new variations are unfortunately likely to arise as scientific methods progress, research misconduct generally falls into one of the following areas:

- Unethical treatment of research subjects.
- Fabrication of data.
- Falsification of data.
- Plagiarism.

As a general guide, the term “research misconduct” applies to any action that involves mistreatment of research subjects or purposeful manipulation of the scientific record such that it no longer reflects observed truth. A Council of Science Editors Consensus Conference on Misconduct in Biomedical Research in October 1999 led to the following broad definition of misconduct:

“Behaviour by a researcher, intentional or not, that falls short of good ethical and scientific standard” (<http://www.publicationethics.org.uk/reports/2000/2000pdf5.pdf>). This section attempts to objectively define research practices that do not meet these subjective standards.

The concepts of negligence and deceit are central to the definition of research misconduct. Not every instance of harm to a research subject is necessarily the result of research misconduct. However, editors and others should consider research misconduct in circumstances where the harm occurs in the setting of or as a direct result of research practices that do not meet ethical norms or as a direct result of irresponsible behavior of the investigator. Similarly, not all inaccurate reports of data are the result of misconduct. For example, the Wellcome Trust, Britain’s largest biomedical charity, specifically states that research misconduct does not include honest error or honest differences in the design, execution, interpretation, or judgment in evaluating research methods or results.<sup>9</sup> Poor-quality research is not misconduct unless the investigators used poor-quality methods with the intention to deceive or without regard to the harm that might befall subjects.

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9. Fraud and misconduct in medical research: causes, investigation and prevention: a report of the Royal College of Physicians. *J R Coll Physicians Lond.* 1991;25:89-94.



### 3.1.1 Mistreatment of Research Subjects

Researchers have an obligation to the subjects they study. These obligations apply whether the subjects are humans or animals and whether the entire organism is being studied or specimens are being taken. When research involves human subjects or their specimens, failure to adhere to the principles in the Declaration of Helsinki<sup>10</sup> and to seek approval from and adhere to the ethical standards of the appropriate institutional or national committee on human experimentation is a serious form of scientific misconduct. For researchers who study animals, failure to follow institutional or national recommendations for the care and use of laboratory animals is also a type of research misconduct.

The following are examples of actions that constitute mistreatment of research subjects:

- Failure to obtain approval from an ethical review board before starting the study.
- Absent or inadequate informed consent of human subjects.
- Maltreatment of laboratory animals.
- Exposure of subjects to physical or psychological harm without informing them of the potential for harm.
- Exposure of subjects (or the environment) to harm because research practices/protocols do not meet accepted and/or specified standards.
- Failure to maintain confidentiality of human data without specific consent from the subject.

The International Committee of Medical Journal Editors addresses this last issue in the Uniform Requirements for Manuscripts Submitted to Biomedical Journals (<http://www.icmje.org>):

Patients have a right to privacy that should not be infringed without informed consent. Identifying information, including patients' names, initials, or hospital numbers, should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that a patient who is identifiable be shown the manuscript to be published.

### 3.1.2 Falsification and Fabrication of Data

Perhaps the most blatant and easy to define (although not always easy to detect) form of research misconduct is when investigators fabricate or falsify data. Fabrication refers to the invention, recording, or reporting of false data.

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10. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA*. 2000;284:3043-3045.

Falsification refers to the alteration of research materials, equipment, protocols, data, or results. Fabrication and falsification are 2 points along a spectrum, but both are serious forms of misconduct because they result in a scientific record that does not accurately reflect observed truth.

### 3.1.3 Piracy and Plagiarism

Piracy is defined as the appropriation of ideas, data, or methods from others without adequate permission or acknowledgment. Again, deceit plays a central role in this form of misconduct. The intent is the untruthful portrayal of the ideas or methods as one's own.

Plagiarism is a form of piracy that involves the use of text or other items (figures, images, tables) without permission or acknowledgment of the source of these materials. Plagiarism generally involves the use of materials from others but can apply to researchers duplicating their own previous reports without acknowledging that they are doing so (sometimes called self-plagiarism or duplicate publication).

*(Authorship: Christine Laine took the lead in writing this section of the white paper on behalf of the CSE Policy Committee. Members of the Policy Committee and the CSE Board of Directors reviewed and commented on it. This section was formally approved by the CSE Board of Directors on September 13, 2006.)*

## Resources and Case Studies

*The COPE Report 2000.* Joint Consensus Conference on Misconduct in Biomedical Research: 28th and 29th October 1999: Consensus Statement. Available at: [www.publicationethics.org.uk/reports/2000/2000pdf5.pdf](http://www.publicationethics.org.uk/reports/2000/2000pdf5.pdf) Accessed April 17, 2006.

International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Available at: <http://www.icmje.org>. Accessed April 17, 2006.

## 3.2 International Models for Responding to Research Misconduct

As improved (and electronic) communication brings the scientific community closer together, cultural variation among scientists and norms for conducting and reporting research become more important. The following section explores the different international models for responding to scientific/research/academic misconduct, including the varied definitions used by the organizations that investigate scientific misconduct, the processes (both formal and informal), and the sanctions and corrective actions taken after the conclusion of an investigation.

### 3.2.1 National Bodies Responding to the Problem

Fairly few countries have developed national means of responding to allegations of scientific misconduct. Formal governmental mechanisms exist or are in development in Australia, Canada, Denmark, Finland, Germany, Norway,





Sweden, and the United States. The most formal, developed, and experienced systems exist in the United States and Denmark. Other countries, such as Great Britain, have addressed the problem through largely private bodies.<sup>11</sup>

The governmental bodies that respond to cases of alleged scientific misconduct have a variety of roles. Under most systems, the research institution employing the accused scientist is responsible for investigating an allegation of research misconduct.<sup>12</sup> This is appropriate because they will have access to the personnel and records necessary to conduct a credible investigation. Further, as the recipient of government funds, they should have responsibility for addressing such allegations. Accordingly, most of the governmental bodies<sup>13</sup> serve review and appellate functions for university and research institution investigations and only conduct the primary investigation if apparent conflicts of interest exist within an institution, the institution lacks the necessary resources, or multiple institutions are involved and it is impractical and inefficient for the institutions to investigate the matter themselves. Nonetheless, in some countries governmental bodies are responsible for conducting the primary investigation of an allegation of research misconduct.

Many of the national bodies were created in the early 1990s. One of the oldest governmental bodies exists in the United States. In the United States before 1989, scientific misconduct cases were investigated by individual granting agencies. In 1989, the Office of Scientific Integrity (OSI), part of the United States National Institutes of Health, and the Office of Scientific Integrity Review (OSIR), part of the Office of the Assistant Secretary for Health, were created to address Public Health Service scientific misconduct cases. The offices were staffed with scientists and attorneys were consulted periodically. In 1992, OSI and OSIR merged to create the Office of Research Integrity (ORI). The ORI professional staff is composed of scientists and lawyers. The National Science Foundation (NSF) is the other US federal body that has been most active in the area of scientific misconduct since 1988. It too has blended law and science when evaluating such cases. Other US federal agencies have addressed cases of misconduct, but none have as much experience as the NSF and ORI.

The Nordic countries have been active in establishing national bodies that respond to the problem. The Danish system, established in 1992, is administered

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11. The main response to the issue has been through the Association of the British Pharmaceutical Industry, the various Royal Colleges, the Committee on Publication Ethics (COPE) (a body comprising editors of top medical journals), and MedicoLegal Investigations, a private agency that since 1996 has investigated 52 studies and 16 doctors.
  12. This is true under the Australian, Canadian and US systems.
  13. This is true under the model adopted in the Finland, Sweden, and the United States.



by the Danish Committee on Scientific Dishonesty (DCSD), an 8-member committee composed of a High Court Judge and 7 senior medical researchers. During 2004, the committee upheld 1 of 11 cases reported, although in neither case did they find intent or gross negligence. The criteria against which scientific dishonesty are judged are “the existence of falsification or distortion of a scientific message or gross misrepresentation about a person’s involvement in the research” (Danish Executive Order No. 933, 15 December 1998, section 3, subsection 1).<sup>14</sup> Annual reports are available (in English) at: [http://forsk.dk/portal/page/pr04/FIST/FORSIDE/DIVERSE\\_SIDER/DANISH\\_RESEARCH\\_AGENCY/THE\\_DANISH\\_RESEARCH\\_COUNSELLING\\_SYSTEM/THE\\_DANISH\\_COMMITTEES\\_ON\\_SCIENTIFIC\\_DISHONESTY/PUBLICATIONS](http://forsk.dk/portal/page/pr04/FIST/FORSIDE/DIVERSE_SIDER/DANISH_RESEARCH_AGENCY/THE_DANISH_RESEARCH_COUNSELLING_SYSTEM/THE_DANISH_COMMITTEES_ON_SCIENTIFIC_DISHONESTY/PUBLICATIONS). Decisions can be appealed to the Ministry of Science, Technology, and Innovation.

In November 1994, the Research Council of Norway also established an 8-member national committee composed of active researchers nominated by the research community and at least one judge. Also in 1994, Finland established a decentralized system under which the Finnish National Research Ethics Committee, comprising 12 members (a university chancellor, 6 professors, a theologian, and 4 civil servants), serves as an appellate body. As of 1999, the National Research Ethics Council of Finland, which is appointed for 3 years by the Council of State, published guidelines for the prevention, handling, and investigation of misconduct and fraud in scientific research. Finally, in 1997, the Swedish Medical Research Council established a 10-member working group chaired by a judge from the Supreme Administrative Court and including a representative from each of the medical faculties in the country (5 individuals), a representative from the Swedish National Agency for Social Affairs, a representative from the National Medical Product Agency, and 2 laypersons who serve on county council hospital boards.

In 1990, the Australian National Health and Medical Research Council passed a set of guidelines and procedures to be implemented by all institutions applying for grants. In New Zealand, there is no formal central organization dealing with research misconduct. If misconduct is suspected, it is usual practice to report the matter to the researcher’s institution or to an appropriate government agency, such as the Health Research Council, if they have funded the research. Aggrieved doctors can also report their concerns to the New Zealand Medical Council or to the Health and Disability Commission if the ethics of research relates to patients. One problem is that the country is sufficiently small that, as one editor put it, “one hint of a problem and everyone knows.”

In Canada, the Tri-Council—comprising the Medical Research Council of Canada, the Natural Sciences and Engineering Research Council of Canada, and

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14. Annual reports are available (in English) at <http://www.forsk.dk/eng/uvvu/publ/index.htm>.



the Social Sciences and Humanities Research Council of Canada, each of which is a Crown corporation independent of the government—has encouraged universities and other institutions to develop specific guidelines that address “research integrity issues.” Institutions were required to have adopted such guidelines by January 30, 1995, or lose their eligibility for federal research funds. In 2004, the Tri-Council published a detailed statement on scientific misconduct in research and scholarship.

The *Canadian Medical Association Journal*, the largest medical journal in the country, employs a single individual who serves both as an ethicist and an ombudsman. After an author has responded to an allegation or suspicion of misconduct, the matter is discussed with the ethicist. After receiving the advice the editors may take further action, which in some instances has involved notifying the institution involved or, in cases where there is no institution identified, informing the physician-licensing authorities or similar professional bodies. It is unclear if editors of smaller subspecialty journals in Canada have similar procedures. There is no national or provincial body in Canada devoted to the investigation of cases of possible research misconduct.

In Britain, because no inspectorate exists and because industry has had most of the cases thus far, activity on this problem has been based on referrals by the Association of the British Pharmaceutical Industry to the General Medical Council (GMC).<sup>15</sup> Two other bodies in the United Kingdom have been advocating institutional reform to address allegations of misconduct: COPE and the Association of Medical Research Charities (AMRC).

COPE is a non-statutory voluntary organization whose members include publishers and editors of nearly 300 journals from throughout Europe, as well as some in Asia and Australasia, whose editors and publishers have adopted the COPE code of conduct (<http://www.publicationethics.org.uk/>). It meets bimonthly, with any member entitled to attend and all members encouraged to submit cases for debate. Its council, which determines policy, comprises 4 editors from premier research journals, two publishers, an ethicist, and two freelance writers and trainers.

At the bimonthly COPE meetings, each case is discussed and advice in line with the code of conduct is given to the submitting editor. In general this means that when the group agrees there may be misconduct it advises the editor to obtain a response from the author(s). When the response is unsatisfactory, the editor typically contacts the authors’ institution and/or funding body and asks them to investigate. Editors are encouraged to request the results of the investigation periodically because some institutions are notorious for delaying. When editors believe patients may be at risk from the research, or when grossly unethical behavior has

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15. Lock S, Wells F, eds. *Fraud and Misconduct in Medical Research*. London, England: BMJ Publishing Group; 1996.



occurred, they may wish to report this to the national body with which the researcher is registered or which gives him or her a license to practice.

In the United Kingdom, governance rules require that an editor who is a practicing clinician or medical researcher and registered with the GMC has a duty to report to that organization any other registered member whose conduct or performance may be significantly impaired. This would include allegations of unethical research and dishonesty in any form. A finding of impaired fitness to practice owing to the above reasons could result in the doctor's registration being affected, either by conditions being placed on his or her work (such as a prohibition from conducting research for a certain period or demanding that all work is closely supervised and approved), suspension from clinical practice for up to a year (which by implication results in a heavy fine, because the doctor may not have an income during that time), or even erasure from the register. The last of these is reserved for very serious cases and has been used in at least one case of research fraud. The GMC is a statutory body whose activities are governed by the Medical Act. Its decisions can be appealed to the High Court.

During the last 10 years the GMC has charged 18 doctors with serious professional misconduct as a result of alleged research misconduct. Nearly all of these cases were reported to the GMC by a private investigative body set up by the Association of the British Pharmaceutical Industry. Publication was not an issue in most of the cases but rather misconduct or dishonesty in carrying out or recording data in industry-sponsored multicenter trials.

In December 2004, COPE adopted a code of conduct for editors who are members of the organization. Complaints about editors that cannot be settled within the auspices of the journal concerned will be investigated and an ombudsman has been appointed to deal with appeal procedures. The organization's major limitation is that it is advisory and cannot apply sanctions (other than to expel a member). So far attempts to set up a system similar to that in the United States or Denmark have not succeeded, but organizations representing industry and universities, as well as COPE itself, are exerting pressure to set up a more widely based and formally constituted body.

In April 2006, the UK Panel on Biomedical and Health Research Integrity was launched. Its board includes representatives from the UK Department of Health, the National Health Service Executive, Universities UK, Medical Research Council, Association of British Pharmaceutical Industry, the Committee on Publication Ethics and other interested parties.<sup>16</sup>

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16. The main response to the issue has been through the Association of the British Pharmaceutical Industry, the various Royal Colleges, the Committee on Publication Ethics ("COPE"), a body comprised of editors of top medical journals and MedicoLegal Investigations, a private agency that since 1996 has investigated 52 studies and 16 doctors.



In December 1997, the Medical Research Council (MRC), the major source of support for biomedical research in the United Kingdom, adopted a policy and procedure for responding to allegations of misconduct. The AMRC has advocated tighter regulations for responding to allegations of misconduct than those imposed by the MRC.

In 1997, in Germany, Deutsche Forschungsgemeinschaft (DFG), the main granting agency in Germany, created an international commission composed of 7 to 10 prominent scientists to discuss research standards and scientific oversight procedures that may be adopted in Germany and internationally. The DFG issued guidelines, required the appointment of mediators, and in 2001 started to threaten to withhold funding from non-complying institutions. The DFG also appointed 3 ombudsmen to receive complaints. The DFG currently has a standing committee called the Committee of Inquiry on Allegations of Scientific Misconduct and established a chair with 4 additional scientists. Further, the Max Planck Society for the Advancement of the Sciences, the premier research organization in Germany, developed guidelines and procedures for detecting, assessing, and imposing sanctions on research fraud in November 1997 (amended in November 2000), titled “Rules of Procedure in Cases of Suspected Scientific Misconduct.”

In China, Beijing University recently published rules to eradicate research misconduct, which was defined as including plagiarism, falsification, and fabrication; publishing results without appraisal from the university authorities or another academic organization; breaching confidentiality; and “intentionally exaggerating the academic value and economic and social results of a research finding.”

In Croatia, the Ministry of Science, Education, and Sports (which funds research) has started introducing regulation in the field of science publishing, primarily prompted by journal publishers and editors. Individual editors sometimes pursue cases in a manner similar to that advised by COPE but many say they are unaware of the research and regulation in the field of research misconduct.

In 2003, the Council of Japan issued a comprehensive report on research misconduct in Japan and recommended that allegations of research misconduct be investigated by third-party committees run by national ministries or scientific societies rather than universities or institutes.

Many countries have not developed a national body to respond to scientific misconduct despite widespread awareness of the problem.<sup>17</sup> Although other organizations exist to address problems relating to misuse of animals or

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17. See Korst M, Axelsen N. *The Danish Committee on Scientific Dishonesty, Annual Report 1995* (chapter 6, “International Developments,” pp 57-73) for a discussion of scientific misconduct experiences and developments in other countries.



humans in experimentation, radiation handling violations, and financial misconduct with research dollars, the advent of organizations that address other forms of scientific misconduct is relatively recent.

### 3.2.2 Definition of Research Misconduct

The responsibility of these bodies is dictated by the definition of scientific misconduct that is used. Unfortunately, a single definition of scientific misconduct does not exist in the scientific community, although most definitions include falsification, fabrication, and plagiarism. This multiplicity of definitions can be explained in part by the multiple national bodies within a country that may be attempting to address the problem. Further, in most countries that have developed a formal response, universities and research institutions are encouraged to develop their own definitions and responses, provided the definitions and processes contain elements mandated by national regulations. Finally, the definitions of misconduct are influenced by the legal structure of the countries in which they exist, the nature of the national body that has assumed the greatest responsibility for responding to the problem, and the ethical norms of the scientific community.

The definitional problem is exacerbated in countries in which multiple bodies have been involved in responding to the problem. For example, in Great Britain, the Association of the British Pharmaceutical Industry defines “research fraud” as the generation of false data with an intent to deceive, and the Royal College of Physicians defines “scientific misconduct” as piracy, plagiarism, and fraud.<sup>18</sup>

In contrast, the MRC defines scientific misconduct as:

fabrication, falsification, plagiarism, or deception in proposing, carrying out, or reporting results of research and deliberate, dangerous, or negligent deviations from accepted practice in carrying out research. It includes failure to follow established protocols if this results in unreasonable risk or harm to human beings, other vertebrates, or the environment and also the facilitating of misconduct by collusion in, or concealment of, such actions by others. Misconduct does not include honest error or honest differences in the design, execution, interpretation, or judgment in evaluating research methods or results of misconduct (including gross misconduct) unrelated to the research process.

COPE defines misconduct as “intention to cause others to regard as true that which is not true.” A 2000 Joint Consensus Conference on Misconduct in

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18. These terms are further defined as follows:

Piracy is the deliberate exploitation of ideas from others without acknowledgment. Plagiarism is the copying of ideas, data or text (or various combinations of the three) without permission or acknowledgment. Fraud involves deliberate deception, usually the invention of data. (*A Report of the Royal College of Physicians, Fraud and Misconduct in Medical Research, Causes, Investigation and Prevention*. London, England: Royal College of Physicians; 1991:3.)





Biomedical Research, which included 10 medical councils, professional societies, foundations and industry in the United Kingdom, led to a broader definition that states “Behaviour by a researcher, intentional or not, that falls short of good ethical and scientific standard.”

The Wellcome Trust, Britain’s largest biomedical charity, defines misconduct as:

Fabrication, falsification, plagiarism or deception in proposing, carrying out, or reporting results of research or deliberate, dangerous or negligent deviations from accepted practices in carrying out research. It includes failure to follow established protocols if this failure results in unreasonable risk or harm to humans, other vertebrates, or the environment and facilitating of misconduct in research by collusion in, or concealment of, such actions by others. It also includes intentional, unauthorized use, disclosure, or removal of or damage to research related property of another including apparatus, materials, writings, data, hardware or software or any other substances or devices used in the conduct of research. It does not include honest error or honest differences in the design, execution, interpretation or judgment in evaluating research methods or results or misconduct unrelated to the research process. Similarly it does not include poor research unless this encompasses the intention to deceive.

Multiple definitions are found even in the United States, which has had the greatest experience and history in handling such cases and has engaged in open and widespread debate regarding the definition of scientific misconduct. These multiple definitions exist despite strong recommendations from the scientific community for a single federal definition. The 2 US agencies most active in matters of scientific misconduct, ORI and NSF, have used different definitions for the past 15 years. In December 2000, however, the White House Office of Science and Technology Policy issued a federal definition of misconduct and encouraged all the agencies, including NSF and ORI to adopt it.

Effective June 16, 2005, the United States Public Health Service, which administers its integrity program through the ORI, defined research misconduct as:

[F]abrication, 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.



The NSF included each component of the Public Health Service definition, and, until April 17, 2002, also included in its definition retaliation against those who bring such allegations. On April 17, 2002, the NSF adopted a definition of misconduct that tracks the White House Office of Science and Technology Policy. Thus, the current NSF definition is:

Research Misconduct means fabrication, falsification, or plagiarism in proposing or performing research funded by NSF, reviewing research proposals submitted to NSF, or in reporting research results funded by NSF.

(1) Fabrication means making up data or results and recording or reporting them.

(2) Falsification means 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.

(3) Plagiarism means the appropriation of another persons' ideas, processes, results or words without giving appropriate credit.

(4) Research, for purposes of paragraph (a) of this section, includes proposals submitted to NSF in all fields of science, engineering, mathematics, and education and results from such proposals.

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

The US federal agencies encourage research institutions to establish their own definitions provided they meet the agencies' basic requirements. Thus, in the United States, the proliferation of definitions occurs at both the federal and institutional level, which makes determinations of misconduct depend on which agency funded the research and at which institution the research occurred.

In the Nordic countries, scientific misconduct is defined broadly and precise definitions are deemed neither desirable nor feasible. The Danish system states:

[A]. Scientific dishonesty includes all deliberate fraudulent work at any time during the application-research-publication process as well as such extreme cases of negligence that the question of professional credibility becomes an issue. This corresponds to the legal concepts of intent and gross negligence.

[B]. The area of scientific dishonesty that is covered by the DCSD is characterized by falsification or distortion of the scientific message or a false credit or emphasis given to a scientist. This includes but is not limited to:

- construction of data
- selective and hidden rejection of undesirable results
- substitution with fictive data
- deliberate manipulation of statistics with the intention of drawing conclusions beyond what the data warrant
- distorted interpretations of results and distortion of conclusions
- plagiarism of other people's results or entire articles



- distorted representations of other scientists' results
- inappropriate credit as author
- misleading applications

Norway has an even broader definition of misconduct that was developed with significant input from the Danish experience. It is simply stated as: "All serious deviation from accepted ethical research practices in proposing, performing and reporting research." It includes (1) fabrication and/or falsification of research results, (2) plagiarism of data or articles, (3) intended selection or withholding of results for publication when those results are relevant to the conclusion, (4) erroneous use of statistical or other methods, (5) intentional or gross negligence in withholding details in methods, (6) erroneous listing of authors, (7) erroneous presentation of research by other investigators, (8) presentation of research to the general public without scientific publication, and (9) unacceptable duplicate publication. The definitions used in Finland and Sweden are similarly broad.

The definition used in the Australian system is the ORI definition verbatim, with a sentence added that addresses inappropriate authorship (ghost authorship, honorary authorship, and failing to acknowledge the contribution of junior scientists).

Violations of human subject regulations constitute scientific misconduct under the British, Canadian, and Danish models. Further, under the Danish and Australian systems, authorship disputes are investigated.<sup>19</sup>

### 3.2.3 The Investigation

As stated earlier, under most systems, the university or research institution has primary responsibility for investigating the allegations of misconduct and then reporting the results of the investigation to a national body. Which US federal agency, if any, has the jurisdiction to address misconduct depends on which federal agency, if any, sponsored or was asked to sponsor the relevant research. If a federal agency did not sponsor the research, no federal agency will have jurisdiction. If the research was funded by the Public Health Service, the ORI has jurisdiction over the case, and the case generally will proceed under ORI guidelines for investigating allegations of scientific misconduct. If the research was funded by the NSF, it will assert jurisdiction.

Institutions are required by US regulation to conduct the investigation of an allegation of scientific misconduct with individuals who have the appropriate

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19. See Case No. 11 from the 1993 cases investigated by the Danish Committee on Scientific Dishonesty and Good Scientific Practice, reported in reference 5 on page 126, and the Australian definition of "scientific misconduct."



expertise and are free from bias. The investigation must follow a prescribed timeline and proof of misconduct must be shown by a preponderance of evidence.

The scientific misconduct findings of ORI and NSF may be appealed. Thus far, only ORI findings have been appealed. The final step in the Public Health Service process may involve an appeal to an administrative law judge who may ask for scientific assistance. In the United States, only 2 cases heard by the final appeal body have included a scientist.<sup>20</sup> In 1999, the PHS indicated that it intended to recompose the panel such that it always included 2 scientists. But in regulations proposed in April 2004, ORI indicated that it would move away from a panel and allow all cases to be heard by an administrative law judge, who would have the latitude to hire a scientific expert.

A similar appeal panel exists under the Danish system, which has 3 members and 3 substitutes, with a significant distinction being that 2 of the members and 2 of the substitutes must be active researchers. Similarly, under the model recommended by the MRC, “scientifically expert assessors evaluate the evidence and draw conclusions.”<sup>21</sup> Under the MRC process, the respondent has access to all material relevant to the allegation, its assessment, investigation, and appeal. Under the English MRC system, an appeal must be filed within 20 days after notice of appeal is sent.

In September 1999, COPE provided editors with guidance on how to respond to misconduct when it arose. Nonetheless, most agree that although a role exists for editors who detect misconduct, editors generally lack the resources and access to the necessary parties and documents to conduct a full investigation.

### 3.2.4 Post-Investigation Issues

**Sanctions.** Individuals found to have engaged in scientific misconduct, as defined by the relevant national norm, have had a variety of sanctions imposed by the institution that employed them, the relevant national body, and professional societies. These sanctions range from letters of censure from an academic superior to a prohibition from receiving federal funds and loss of a professional medical license. In the United Kingdom, 9 of 10 doctors referred for findings of misconduct were suspended or removed from the medical register. In contrast, in a case in Poland,<sup>22</sup> no action was taken because under Polish higher-education law action must be taken within 3 years of the offense and too much time had elapsed between the alleged plagiarism and its detection.

20. Parrish D. Improving the scientific misconduct hearing process. *JAMA*. 1997;277:1315-1319.

21. Evans I. Dealing with research misconduct in the United Kingdom: conduct unbecoming: the MRC's approach. *BMJ*. 1998;316:1728-1729.

22. Zawadzki Z, Abbasi K. Polish plagiarism scandal unearthed. *BMJ*. 1998;316:645. Available at: <http://bmj.bmjournals.com/cgi/content/full/316/7132/645> Accessed May 4, 2006.



Recovery of research funds associated with scientific misconduct has not been pursued in countries other than the United States, although it is being considered in Canada.

**Confidentiality of findings.** Multiple philosophies exist regarding post-investigation sanctions and corrective action. The ORI widely publicizes the names of those it finds guilty of misconduct, and the full reports of its investigations and of the university investigations that were provided to it are available with limited information masked. In contrast, the NSF does not provide the names of guilty individuals, and their names are removed from its reports. Similarly, the Danish Committee on Scientific Dishonesty does not publish the names of scientists found to have committed scientific misconduct. Under the United Kingdom's MRC process, the scientific community, sponsors and other "interested parties" are informed of findings of misconduct.

*(Authorship: Debra Parrish and Harvey Marcovitch took the lead in writing this section of the white paper on behalf of the CSE Policy Committee. Members of the Policy Committee and the CSE Board of Directors reviewed and commented on it. This section was formally approved by the CSE Board of Directors on September 13, 2006.)*

### 3.3 Reporting Suspect Manuscripts

There have been a number of cases involving allegations of misconduct and manuscripts including some considered by the Office of Research Integrity (ORI; part of the US Public Health Service) and the National Science Foundation (NSF). Cases also exist in which the allegation regarding misconduct is made even before the manuscript is submitted to a journal. For example, even showing a draft of a manuscript that contains falsified data to collaborators has served as the basis of a misconduct allegation. This section will focus on manuscripts that have been submitted to journals but not yet published. In addition to the advice rendered by ORI and NSF, the Committee on Publication Ethics (<http://www.publicationethics.org.uk/>) has provided advice to journal editors regarding the handling of suspect manuscripts. This section will review 2 issues: From whom should a journal accept allegations of misconduct with respect to a manuscript? Whom should a journal notify when its agents (eg, editor, staff or reviewers) are the source of the allegation?

#### 3.3.1 Who Might Notify A Journal About A Suspect Manuscript?

A number of parties can identify a manuscript wherein the content or authorship is the subject of an allegation of misconduct (herein termed a *suspect manuscript*). These parties include editors, reviewers, authors, colleagues, third-party observers, and anonymous sources. Editors have identified suspect manuscripts through screening mechanisms for image manipulation, because they recognize the text or data from a prior submission, or because they have



read of allegations of misconduct in other sources. Reviewers have questioned data that appear too neat or have noticed their own work being submitted by another. Typically, if any author is going to identify a suspect manuscript for the editor, it will be the co-author who has been accused of misconduct, although other authors have provided such notice if the accused author hesitates to do so. Often an accused author is required by his or her institution to send notice to a journal to withdraw a manuscript after an allegation is made. The notice to the journal typically does not indicate that the manuscript is the subject of a misconduct investigation unless the notice is provided after a finding of misconduct has been made. Institutions typically require withdrawal of a suspect manuscript early in the misconduct investigation process to avoid having to later retract an accepted manuscript. As a condition of settlement as or as a sanction imposed after a finding of misconduct, the ORI requires an accused author to send notification to a journal requesting appropriate corrective action with respect to a suspect manuscript.

Disaffected colleagues sometimes identify a problematic manuscript, typically when they have been omitted as co-authors and believe that pursuing publication without a byline listing constitutes plagiarism. Third parties, such as a journal's readers, have identified suspect articles to editors when they note a similarity to other published articles. At the time of this writing, it does not appear that any federal agencies or anonymous sources have yet provided notice to a journal editor regarding a suspect manuscript.

### 3.3.2 Whom Should a Journal Notify About a Suspect Manuscript?

If he or she suspects an article contains material that may result in a finding of misconduct, the editor can notify some or all of the following parties: the author who submitted the article, all the authors of the article, the institution that employs the author(s), the sponsor of the study, or an agency that would have jurisdiction over an investigation of the matter (eg, the ORI). Or the editor may choose to notify no one. In fact, an editor of *History News Network* indicated that he got so many allegations of plagiarism that he referred only the most notorious cases for investigation.<sup>23</sup> It appears that most editors have chosen to notify the corresponding author of a problem with a manuscript. This approach has the advantages of both identifying a potential problem without initiating the required steps in a misconduct investigation and minimizing potential unnecessary harm to an author. The corresponding author often can identify which author is responsible for the suspect portion of the manuscript without unnecessarily involving the other authors. Some editors

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23. Bartlett T, Smallwood S. Four academic plagiarists you've never heard of: how many more are out there? *Chronicle of Higher Education*. 2004;51:A8. Available at: <http://chronicle.com/free/v51/i17/17a00802.htm>. Accessed April 28, 2006.





might attempt to contact all the authors in the interest of receiving a prompt response, but this potentially increases the risk for a breach of confidentiality and that the same inquiry will result in different responses from multiple authors and institutions (for example, one institution might require the reporting of potential allegations of misconduct, while another institution might wait until a formal allegation is made). Also, authors who are not responsible for the suspect portion of the manuscript are more likely to invoke protective processes to prevent the opening of an investigation at their institution on receiving a letter from a journal editor. Authors may also attempt to destroy or discard evidence and thus inhibit the ability of institutional authorities to resolve the issue.

If the author's response is not satisfactory, many editors notify the employing institution because the institution typically will have access to the source material, the means to conduct an investigation, the ability to compel an author's participation in the investigation, and the ability to impose sanctions. In the United States, by regulation, institutions have the primary responsibility to conduct investigations of misconduct allegations. Nonetheless, notifying an author's institution should not be a reflex reaction for editors. Editors should consider the impact such notification may have on the career of the accused scientist. Relatively few editors opt to notify the relevant federal agency because the jurisdiction of the agencies is often unclear when a manuscript is submitted and because the agencies will only refer the matter to the employing institution for investigation. Also, notification of a federal agency makes the journal the accuser and creates a role for the journal in a misconduct investigation whether the journal wants one or not.

Few editors undertake investigations into misconduct allegations themselves. Journals often lack access to the necessary materials or resources to conduct an investigation, and most have not adopted a definition of misconduct or established policies and procedures for conducting such investigations. Further, few editors have experience or expertise in conducting such investigations or in the nuances of the various definitions of misconduct being used by the scientific community. Because a finding of scientific misconduct typically has profound professional implications for a researcher, a journal conducting an investigation should anticipate various challenges, including legal challenges. Editors should proceed with caution before undertaking such an investigation. Although no editor has successfully been sued for taking action in a misconduct cases, several threats of such action have been made by counsel in such cases.

*(Authorship: Debra Parrish took the lead in writing this section of the white paper on behalf of the CSE Policy Committee. Members of the Policy Committee and the CSE Board of Directors reviewed and commented on it. This section was formally approved by the CSE Board of Directors on September 13, 2006.)*

### 3.4 Digital Images and Misconduct

The revolution in electronic communication has meant that many journals now have completely electronic workflows. Manuscripts, including both text and figures, are submitted as electronic files, which are then imported into layout templates by production departments. Electronic workflows provide for efficient transfer of information and improved reproduction of image data. They also afford journal editors a new opportunity to examine the images in figures for evidence of manipulation.

The ease of image manipulation in powerful applications like Photoshop makes it tempting for authors to adjust or modify digital image files. Authors have been using these applications for more than 10 years; however, during most of this time journals have had paper workflows, which meant that editors only saw a printout of the images and could not examine the image files. Electronic workflows make these files available to journal editors. With simple forensic techniques, manipulations can be revealed that would not have been visible on a printout. Many of the manipulations that are detected constitute inappropriate changes to the original data and may indicate that scientific misconduct has occurred. In more egregious cases, such manipulations may constitute blatant fraud. For the purposes of this document, *fraud* is defined as falsification or fabrication of image data; it is not meant to encompass the legal criteria of intent or harm to a third party who relied on the data.

As editors implement electronic workflows, they have a responsibility to set guidelines for authors on the proper handling of image data. Clear guidelines are important because some level of image manipulation is accepted practice (for example, image cropping or limited adjustment of brightness and contrast), and authors must understand the boundary between acceptable and unacceptable manipulation.

After guidelines are established, editors have a responsibility to enforce them. To do so requires the establishment of definitions of misconduct, procedures for identifying misconduct, and policies for handling misconduct.

Guidelines developed by The Rockefeller University Press have been published elsewhere (along with examples of different types of manipulation).<sup>24</sup> This section will primarily discuss how the journal editor should enforce these guidelines.

#### 3.4.1 Guidelines for Handling Image Data

The Rockefeller University Press has established 4 basic guidelines:

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24. Rossner M, Yamada K. What's in a picture: the temptation of image manipulation. *J Cell Biol.* 2004;166:11-15.



- No specific feature within an image may be enhanced, obscured, moved, removed, or introduced.
- Adjustments of brightness, contrast, or color balance are acceptable if they are applied to the whole image and as long as they do not obscure, eliminate, or misrepresent any information present in the original.
- The grouping of images from different parts of the same gel, or from different gels, fields, or exposures must be made explicit by the arrangement of the figure (eg, dividing lines) and in the text of the figure legend.
- If the original data cannot be produced by an author when asked to provide it, the acceptance of the manuscript may be revoked.

These comprehensive guidelines were developed in 2002 and are used by the journals published by The Rockefeller University Press. We hope that other journals will consider using them.

### 3.4.2 Enforcing the Guidelines

**Examining image files.** In an electronic workflow, a production editor will have to examine each figure file for compliance with journal requirements such as file type, resolution, and image size. At the same time, the production editor can do a “forensic” analysis of the images in a figure file. For grayscale images, adjustments to brightness and contrast using the basic “Brightness/Contrast” slide bars in Photoshop can reveal inconsistencies in the pattern of background pixelation that are clues to manipulation. For color images, more sophisticated adjustments to contrast using the “Levels” slides may be necessary to reveal inconsistencies; a clear example is provided in Figure 6 of reference 23.

**Defining misconduct.** The Rockefeller University Press has defined 2 types of digital image-related misconduct: inappropriate manipulation and fraudulent manipulation. Inappropriate manipulation refers to an adjustment to the image data that violates guidelines but does not affect the interpretation of the data. Examples include adjustments of brightness/contrast to a gel image that completely eliminate the background (so the reader cannot tell how much of a gel is shown) or that obscure background smears or faint background bands. Another example is the splicing together of images from different microscope fields into a single image that appears to be a single field. Fraudulent manipulation refers to an adjustment to an image that affects the interpretation of the data. Examples include deleting a band from a gel to “fix” a negative control that did not work or adding a band to a gel to indicate the presence of product that was not really there.

**Handling misconduct.** If a production editor detects a clear case of “inappropriate manipulation,” he or she can request that the author resubmit the figure in question with a more accurate representation of the original data. This approach only applies to adjustments for which there is a clear solution to



remedy the problem; for example, lines need to be added to a gel image to indicate that lanes have been spliced out. In such cases, it is not necessary to request the original data from the author. If the production editor thinks there is any possibility that the manipulation may be fraudulent, the journal editor should be alerted, and the original data from the authors should be obtained for comparison to the prepared figure. Although the ORI guidelines for editors indicate that cases of “suspected” misconduct should be reported either to the ORI or to an author’s institution,<sup>25</sup> journal editors should attempt to resolve the problem before a case is reported. This is because the vast majority of cases do not turn out to be fraudulent.

**Obtaining original data.** Authors’ reputations for impeccable research integrity amongst their scientific peers are vital for success in their careers. Authors will thus be concerned (with good reason) when the integrity of the data in a manuscript accepted for publication is questioned. It is important for an editor to reassure authors at this initial stage of investigation that only the presentation of the data is being questioned and not its scientific quality, which has already been vetted by peer reviewers and academic editors. The letter requesting original data can even point out that often the inconsistencies revealed by image “forensics” are simply due to the transfer of images from one computer application to another, for example, from PowerPoint to Photoshop, and that it is possible that no manual adjustments have been made by the authors. In addition, an editor could point out that it is in the authors’ interest to resolve the inconsistencies before the images are published online because they may be questioned by a reader. Authors should also be assured that the inquiries at this stage are strictly confidential between themselves and the journal.

### 3.4.3 Procedure for Handling Guideline Violations

If a comparison of the original data with the prepared figure indicates that images have been inappropriately manipulated but not fraudulently manipulated, the author should simply be asked to remake the figures with a more accurate representation of the original data.

If the comparison reveals that fraudulent manipulation has occurred, the first step is to revoke acceptance of the paper. At the *Journal of Cell Biology*, the conclusion that fraudulent manipulation has occurred must be agreed on by 4 people before such action is taken: the managing editor (a PhD scientist), the academic monitoring editor, the academic senior editor, and the academic editor-in-chief.

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25. Office of Public Health and Science. Managing allegations of scientific misconduct: a guidance document for editors. Available at: [http://ori.dhhs.gov/documents/masm\\_2000.pdf](http://ori.dhhs.gov/documents/masm_2000.pdf). Accessed May 1, 2006.



A policy for reporting misconduct should be developed by each journal (see 3.1, 3.2, and 3.3.) Reporting can be done either to an author's institution or to the ORI (<http://ori.dhhs.gov/>). The *Journal of Cell Biology* does not report digital image-related misconduct if the principal investigator takes responsibility for the action and indicates that measures have been taken to avoid image manipulation in the future.

If a journal decides to report misconduct to an author's institution, many institutions that receive Public Health Service (PHS) funding have an Ombudsman for Allegations of Misconduct in Science. If not, every institution that receives PHS funding has an individual who has signed the PHS "Letter of Assurance," which indicates that they will abide by the PHS code of conduct.

*(Authorship: Michael Rossner took the lead in writing this section of the white paper on behalf of the CSE Policy Committee. Members of the Policy Committee and the CSE Board of Directors reviewed and commented on it. This section was formally approved by the CSE Board of Directors on September 13, 2006.)*

### 3.5 Correcting the Literature

Correcting the literature is a critical part of the research enterprise for a variety of reasons. First, it addresses unreliable information that is part of the public record. Second, once corrected, it enables the researcher to identify and use correct information, thereby saving time and resources. Third, it enhances a journal's reputation by taking a proactive role in publishing accurate information for its readership.

Because of the breadth of the scientific culture, it is important to note that there is not one recognized method for addressing literature corrections. Of the various scientific disciplines reviewed for this section, the biomedical sciences have had the most experience in addressing literature correction issues. Hence, the information in this section is built largely on the literature correction policies of 2 organizations that have had extensive experience in this area, the National Library of Medicine (NLM) and the International Committee of Medical Journal Editors (ICMJE).

The NLM is the largest medical library in the world, serves millions of researchers through MEDLINE, and develops policies annually in response to issues that surface in the biomedical publishing community. The Uniform Requirements for Manuscripts Submitted to Biomedical Journals (<http://www.icmje.org/>), which are endorsed by more than 500 journals, reflect the experiences of editors since 1978 and are updated regularly to address new issues in scientific publication. The guidelines of both these organizations provide a useful framework to the greater scientific research community for addressing the issues related to correcting the literature.



The following sections will examine the state of the art for literature corrections, including definitions, processes, a checklist for editors, and examples for language used for correcting the literature.

### 3.5.1 Definitions

One of the most confusing aspects associated with literature corrections are the terms journals use when identifying what is being corrected. Different terms are sometimes used interchangeably. For example, the term *retraction* is not applied by journals uniformly. Some journals will use the term *erratum* for a retraction and this can lead to confusion for the reader. For the purpose of this document, the definitions used by the NLM will serve as the gold standard for literature correction terminology.

The primary methods used for correcting the literature are errata and retractions.

- **Errata.** Published changes or emendations to an earlier article, frequently referred to as *corrections* or *corrigenda*, are considered by NLM to be errata, regardless of the nature or origin of the error. The NLM does not differentiate between errors that originated in the publication process and errors of logic or methodology.
- **Retractions.** Retractions identify a citation that was previously published and is now retracted through a formal issuance from the author, publisher, or other authorized agent. The NLM does not differentiate between articles that are retracted because of honest error and those that are retracted because of scientific misconduct or plagiarism. If the notification in the journal is labeled as a retraction or withdrawal, NLM will index it as a retraction.
- **Expressions of Concern.** This indexing term was introduced by the ICMJE, incorporated into the NLM system in 2004, and has been used on a few occasions.<sup>26,27</sup> The expression of concern is a label that an editor may use to draw attention to possible problems but does not go so far as to retract or correct an article. Examples of this correction format are provided at the end of this section.

### 3.5.2 Published Guidelines

While a wide variety of journals may be aware of literature correction issues, experiences are not uniform, and established policies and procedures often do not exist. Many disciplines have codes of conduct regarding good publishing practices, but few specifically state how literature corrections will be

26. S. Kotzin, Chief, Indexing, MEDLINE; written communication, December 2004.

27. International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Available at: <http://www.icmje.org/#correct>. Accessed April 26, 2006.





addressed. Literature corrections are typically handled on a case-by-case basis.

The American Physical Society published the Supplementary Guidelines on Responsibilities of Coauthors and Collaborators ([http://www.aps.org/statements/02\\_2.cfm#supplementary\\_guidelines](http://www.aps.org/statements/02_2.cfm#supplementary_guidelines)) (adopted by the APS Council on November 10, 2002) and these guidelines discuss authorship responsibilities associated with maintaining integrity in what is published. In addition to addressing authorship responsibilities, the guidelines state that “all coauthors have an obligation to provide prompt retractions or correction of errors in published works. Any individual unwilling or unable to accept appropriate responsibility for a paper should not be a coauthor.”<sup>28</sup> While not all authors who publish are members of the American Physical Sciences, anyone who publishes in their journal is held to these standards.

The Society for Neuroscience has been one of the leading professional societies to address literature corrections due to a finding of scientific misconduct. In their 1998 publication, “Responsible Conduct Regarding Scientific Communication” (<http://web.sfn.org/index.cfm?pagename5responsibleConduct>), the society outlines the following steps:

If an investigation concerning a published article or abstract determines that the article contains a serious error, then a correction or retraction must be published prominently in the journal or abstract collection in which the original report appeared and contain the full bibliographic reference to the article or abstract. It should also be listed in the contents page and be prominently labeled (eg, erratum, retraction, or apology).

If the article or abstract was authored by more than one individual and some of those individuals are found to be innocent of misconduct, this should be made clear in the published statement. Any co-authors not found to be guilty of misconduct should be invited to participate in the preparation of the correction or retraction and/or to add an indication of their agreement to the statement. However, such authors should not be permitted to block publication of the statement.<sup>29</sup>

While many disciplines do address the role of the author and the responsibilities associated with ethical publishing practices, many do not address lit-

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28. American Physical Society. Supplementary guidelines on responsibilities of coauthors and collaborators. Available at: [http://www.aps.org/statements/02\\_2.cfm#supplementary\\_guidelines1](http://www.aps.org/statements/02_2.cfm#supplementary_guidelines1). Accessed April 26, 2006.

29. Society for Neuroscience. Dealing with possible scientific misconduct. Available at: [http://web.sfn.org/index.cfm?pagename5responsibleConduct\\_dealingWithPossibleScientificMisconduct](http://web.sfn.org/index.cfm?pagename5responsibleConduct_dealingWithPossibleScientificMisconduct). Accessed April 26, 2006.



erature corrections. Those fields that do not have an established policy on literature correction issues at this time include botany, chemistry, geophysical science, and veterinary medicine.

### 3.5.3 The US Public Health Service

The US Public Health Service (PHS) Office of Research Integrity (ORI) has had a wide range of experience with journal editors and authors in reference to publications requiring literature corrections due to findings of scientific misconduct.

The ORI is the office within the PHS that is responsible for addressing scientific misconduct and research integrity related to PHS activities. One of the PHS administrative actions requires the respondent to submit a letter to the editor of the journal in which the article is being corrected due to a finding of scientific misconduct. When a respondent is required to submit a retraction or a correction of an article, the respondent must also send a copy of the retraction or correction letter to the ORI.

To ensure that editors are notified about submitted manuscripts or published articles in their journal that require correction or retraction because of findings of scientific misconduct, the ORI sends the editor a letter with a copy of the *Federal Register* notice, the ORI report or the voluntary agreement signed by the respondent, and the Departmental Appeals Board decision, if applicable. This notification is sent on publication of the *Federal Register* notice announcing the PHS findings and administrative actions.<sup>30</sup>

The ORI may request that journals publish corrections or retractions resulting from scientific misconduct cases. Although the ORI does not have authority to require the journal to publish the retraction or correction, it can require the scientist who committed misconduct to submit the request. Besides PHS administrative actions, requests to correct the literature may be initiated by the institution where the misconduct occurred or by a co-author of the questioned paper before the ORI has completed its oversight review. If the request for a retraction is accepted, the editor should publish the retraction as indicated in the Uniform Requirements—meaning it should be labeled as such, appear in a prominent section of the journal, be listed in the table of

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30. The ORI has adopted a target timeline of 480 days for completing misconduct cases that involve research supported by the PHS. The timeline begins with the initiation of an institutional inquiry and concludes with review by the Assistant Secretary for Health. Cases that are appealed to the Departmental Appeals Board (DAB) or investigated by the Office of the Inspector General (OIG) are not included, because the DAB regulation establishes 9 months as a goal for completion of a hearing and the OIG is independent from Departmental supervision. Extensions are granted for reasonable cause. The general timeline can be found at: [http://ori.hhs.gov/misconduct/inquiry\\_issues.shtml](http://ori.hhs.gov/misconduct/inquiry_issues.shtml). Accessed April 26, 2006.



contents, and include in its heading the title and citation of the original journal article.<sup>31</sup>

### 3.5.4 The National Science Foundation, Office of Inspector General

The National Science Foundation, Office of The Inspector General (NSF/OIG) addresses allegations of research misconduct in relation to research funded by the NSF. To date, the NSF/OIG has not addressed scientific misconduct cases that have required literature corrections but relies on a grantee's institution to handle literature corrections related to findings of scientific misconduct.<sup>32</sup>

### 3.5.5 Processes

Literature corrections, whether in the form of errata or retractions, have been made by a variety of "authorized" agents. These agents have included authors, editor(s), publishers, department chairpersons, deans, laboratory directors, and legal counsel. It is important to mention that journals, professional societies, and government bodies have individual policies addressing how literature corrections will be managed. There are very few journals that address literature corrections.<sup>33,34</sup> However, the NLM and Uniform Requirements describe those persons from whom literature corrections will be accepted.

Of the 2 primary forms of literature corrections, "retractions" are sometimes difficult to attain. As indicated by the NLM, retractions are issued for the more serious literature corrections. While they are not issued only when associated with scientific misconduct, they are most easily published when the responsible author(s) submits the request to the editor. History has shown, however, that there are instances in which an author found guilty of scientific misconduct refuses to submit a retraction. Such situations are delicate and vary in difficulty. Because not all journals have policies on how to address literature corrections, editors are sometimes reluctant to publish a retraction without the signature of the author who committed the misconduct. Yet editors

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31. Office of Public Health and Science. Managing allegations of scientific misconduct: a guidance document for editors. Available at: [http://ori.hhs.gov/documents/masm\\_2000.pdf](http://ori.hhs.gov/documents/masm_2000.pdf). Accessed April 26, 2006.
  32. J. Kroll, Head of Administrative Investigation, NSF/OIG; written communication, January 2005.
  33. Scheetz MD. Coming full circle: can misconduct be prevented? Presented at: The Journal's Role in Scientific Misconduct: An Educational Retreat. Leesburg, Va; November 9, 2003.
  34. Scheetz MD. Promoting integrity through instructions to authors: a preliminary analysis. In: Ste-neck NH, Scheetz MD, eds. *Proceedings of the 1st ORI Research Conference on Research Integrity*. Available at: [http://69.59.142.46/documents/instructions\\_authors.pdf](http://69.59.142.46/documents/instructions_authors.pdf). Accessed April 26, 2006.



should consider their responsibility of reporting accurate information to their readership. The ORI has had an example in which coauthors and a responsible university official submitted a retraction when the original author refused.<sup>35</sup> The latter part of this document provides examples of coauthors submitting retractions when an author guilty of misconduct refused.

As previously discussed, the NLM and the Uniform Requirements developed by the ICMJE are the leaders in issuing guidance and instruction on correcting the literature. The following sections outline the processes used by both.

The NLM uses the following processes for addressing errata and retractions:

**Errata.** When a publisher, editor, or author has published a labeled, citable erratum to an article that was cited in the MEDLINE database, NLM has amended the citation of the article with a bibliographic reference to the erratum notice to alert users and refer them to the source of the revised information.

The reference to a published erratum notice is in the form of a notification that appears above the article title in the Abstract or Citation formats of PubMed. In the MEDLINE format, this information appears in the EIN (Erratum in) field. Although errors may occur in any part of the published article, NLM will add the corrected information to the citation if the erroneous data were incorporated in the original MEDLINE citation. That is, if the error occurred in the article's authorship, title, or abstract, NLM will retain the original citation, if it affects retrieval, but will add the revised data to provide the correct information. If an author's name was misspelled, the corrected name is inserted in the appropriate order and the original misspelling is moved to the end of the author list. Thus, a user who wishes to follow up on all of the authors from the journal issue will be able to retrieve on the misspelled name as well. The notice about the correction will show both the incorrect spelling of the name and the corrected form.

If, however, the error occurred in a portion of the article that is not included

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35. An investigation conducted by the University of California, San Francisco, found that an author falsified data in a publication on AIDS research. According to the investigation, he selectively suppressed data that did not support his hypothesis and reported consistently positive data even though only 1 of his 4 experiments had produced positive results. The falsified data were then used as the basis for a grant application to the National Institutes of Health. The ORI concurred in the university's finding. The researcher executed a "voluntary exclusion and settlement agreement" with PHS in which he agreed not to apply for federal grant or contract funds and would not serve on PHS advisory committees, boards, or peer review groups for 3 years. The publication was retracted. When the author refused to agree to a retraction, the *New England Journal of Medicine* published the retraction without his signature but with the signatures of the rest of the coauthors and of the assistant vice chancellor of the university. Case study presented at: The Journal's Role in Scientific Misconduct: An Educational Retreat. Leesburg, Va; November 9, 2003.



in the MEDLINE citation, such as the text, graphs, or tables, only a reference to the published erratum notice will be added to the MEDLINE citation. Brief errata notices are not generally indexed as independent articles. Some substantive articles or letters may, however, comprise published errata. If so, these items will be indexed with the Publication Type PUBLISHED ERRATUM. For those citations having a publication date of 2002 forward, a link will refer back to the citation for the original article. That link appears above the article title in the Abstract or Citation formats of PubMed while in the MEDLINE format the information appears in the EFR (Erratum for) field.

It is NLM's policy that errata will be acknowledged only if they are printed in a citable form; that is, an erratum notice must appear on a numbered page in an issue of the journal that originally published the article. Error notices that are inserted unbound into a journal issue or "tipped" will not be considered part of the permanent bibliographic record. An erratum notice pertaining to a portion of a journal that exists in online format only must be readily discernable in the table of contents of a subsequent issue. NLM does not make changes in the database in response to letters from authors or editors, unless such letters indicate that a substantive published erratum is forthcoming.

**Retractions.** Articles may be retracted or withdrawn by their authors, academic or institutional sponsor, editor, or publisher because of pervasive error or unsubstantiated or irreproducible data. It is NLM's policy that a retraction will be indexed as a retraction only if it clearly states that the article in question is being retracted or withdrawn, and is signed by an author of the retracted paper or author's legal counsel; by the head of the department, dean, or director of the laboratory where the paper was produced; or by the journal editor. In addition, the retraction must be labeled and published in citable form; that is, the retraction must appear on a numbered page in an issue of the journal that published the retracted article.

NLM does not simply expunge the citation of a retracted article from its indexes or databases, but rather links the original to the notice of retraction by adding a Retraction statement after the source of the retracted article on the PubMed Summary display. The bibliographic reference for the retraction notice also appears above the title in the Abstract and Citation formats in PubMed. In the MEDLINE format, it appears in the RIN (Retraction in) field. The MEDLINE record of each retracted article will be given an additional Publication Type of RETRACTED PUBLICATION (PT) as well.<sup>36</sup>

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36. National Library of Medicine. Errata, retraction, duplicate publication, comment, update and patient summary policy for MEDLINE. Available at: <http://www.nlm.nih.gov/pubs/factsheets/errata.html>. Accessed April 26, 2006.



NLM makes a reciprocal linkage between the retraction statement and the retracted article. That is, the retraction statement is indexed as RETRACTION OF PUBLICATION (PT). The bibliographic reference(s) for the article(s) being retracted appear above the title in the Abstract and Citations formats in PubMed. In the MEDLINE format, they appear in the ROF (Retraction of) field. Examples of errata and retractions found in MEDLINE can be found at the online NLM fact sheet (<http://www.nlm.nih.gov/pubs/factsheets/errata.html>). The processes to correcting literature corrections for errata and retractions as addressed in the Uniform Requirements are the following:

**Errata.** Errors may be noted in published articles that require the publication of a correction or erratum of part of the work. The corrections should appear on a numbered page, be listed in the contents page, include the complete original citation, and link to the original article and vice versa if online. It is conceivable that an error could be so serious as to vitiate the entire body of the work, but this is unlikely and should be handled by editors and authors on an individual basis. Such an error should not be confused with inadequacies exposed by the emergence of new scientific information in the normal course of research. The latter require no corrections or withdrawals.

**Retractions.** If a fraudulent paper has been published, the journal must print a retraction . . . The retraction or expression of concern, so labeled, should appear on a numbered page in a prominent section of the print journal as well as in the online version, be listed in the contents page, and include in its heading the title of the original article. It should not simply be a letter to the editor. Ideally, the first author should be the same in the retraction as in the article, although under certain circumstances the editor may accept retractions by other responsible persons. The text of the retraction should explain why the article is being retracted and include a full original citation reference to it.

The validity of previous work by the author of a fraudulent paper cannot be assumed. Editors may ask the author's institution to assure them of the validity of earlier work published in their journals or to retract it. If this is not done, editors may choose to publish an announcement expressing concern that the validity of previously published work is uncertain.<sup>37</sup>

### 3.5.6 Editor's Checklist

Because literature corrections may occur at different points throughout the publication process, there is not one specific formula that is applicable in all situations. Editors typically address these matters on a case-by-case basis.

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37. International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Available at: <http://www.icmje.org/#correct>. Accessed April 26, 2006.





However, there are some general issues that an editor should consider when addressing a literature correction:

**What is the nature of the correction request?** Based on the definitions previously outlined, does the literature correction warrant a correction, retraction, or expression of concern? The correction type should be determined by the nature of the correction.

**Who makes the request?** Ideally, the request should be made by the responsible author(s). However, as noted in an earlier section, there are occasions when a third party may need to make the correction due to differences of opinion or disagreements among authors regarding the responsibility for the retraction. The editor's concern should be correcting the literature so the readership can rely on the information published.

**Who writes the correction?** Depending on the situation, the literature correction should be made by the author(s) of the paper being corrected. In those situations where there is disagreement, the correction should be written by a responsible institutional official or the editor.

**What verbiage should be used for the correction?** The readership is best served when the literature correction states what is being corrected. Errata are often typographical errors. Retractions are typically made owing to honest error, or sometimes scientific misconduct. As stated by the ICMJE guidelines, the text of the retraction should explain why the article is being retracted and include the full original citation. Examples of verbiage used are provided at the end of this document.

**When should the correction be published?** Depending on the situation, an editor should publish the correction as soon as reasonably possible. In the case in which the corrections are the product of a scientific misconduct investigation, this would occur after a finding of scientific misconduct had been made by an institution or an oversight agency, if appropriate.

On the rare occasion in which a paper under review for possible scientific misconduct included a public health concern, it would be prudent for the institution conducting the investigation to notify the journal editor of this public health concern. The decision of when to publish a retraction then rests with the editor.

### 3.5.7 Examples of Literature Corrections

In addition to policies varying on how to publish literature corrections, so do the actual publications themselves. The following section provides a variety of literature corrections (errata and retractions), along with identification of who submitted the literature correction. The literature corrections are from publicly available sources and vary in presentation to reflect the authenticity and style of the respective journal.

1. *J Infect Dis.* 2004;190:2059. **Erratum** submitted by authors.

In an article in the 1 November 2004 issue of the Journal (Gumbo T, Louie A, Deziel MR, Parsons LM, Salfinger M, Drusano GL. Selection of a moxifloxacin dose that suppresses drug resistance in *Mycobacterium tuberculosis*, by use of an in vitro pharmacodynamic infection model and mathematical modeling. *J Infect Dis.* 2004;190:1642-51), a ">" should have preceded "1 mg/L" in the sixth line in the right-hand column of page 1644. The authors regret this omission.

2. *Arch Gen Psychiatry.* 2006;63:365. **Erratum** submitted by authors.

Errors in Text. In the Original Article by Birmaher et al titled "Clinical Course of Children and Adolescents With Bipolar Spectrum Disorders," published in the February issue of the ARCHIVES (2006;63:175-183), errors occurred in the text on pages 176 and 179. On page 176, in the "Methods" section, "Subjects" subsection, fifth paragraph, the third sentence should have read as follows: "Subjects with BP-II had the onset of their mood disorders significantly later and had significantly lower rates of comorbid attention-deficit/hyperactivity disorder than subjects with BP-I and BP-NOS ( $P \leq .05$ )." On page 179, under "Weekly Mood Symptomatic Status by BP Subtype," first paragraph, the second sentence should have read as follows: "Within the syndromal symptoms, subjects with BP-I spent significantly more weeks with syndromal mania and mixed symptoms than those with BP-NOS, and subjects with BP-II spent significantly more time with depressive symptoms than those with BP-I and BP-NOS (all comparisons,  $P \leq .001$ )."

3. *Science.* 2004;306:54. **Retraction** submitted by all authors.

In the Report "Synaptic changes in layer 2/3 underlying map plasticity of developing barrel cortex" (Petersen CC, Brecht M, Hahn TT, Sakmann B. *Science.* 2004;304(5671):739-742), we concluded that functional and anatomical changes in layer 2/3 underlie different forms of cortical map plasticity. It was pointed out to us by a reader that the anatomical analysis contains errors. Although these errors did not affect the main conclusions, we re-analyzed the data set. Re-analysis confirmed that whisker stimulation evokes a cortical response, which spreads preferentially to neighboring, nondeprived cortical columns as originally reported. However, the reported difference between the axonal fields in control and deprived animals was not statistically significant. Further, the deprivation-induced decrease in unitary EPSP amplitude was also not statistically significant. Thus, major conclusions of the Report are no longer supported, and we retract the Report. We apologize for any confusion that we may have caused to the readers of *Science*.

4. *Proc Natl Acad Sci U S A.* 2000;97:1949. **Retraction** submitted by co-authors but not the author guilty of scientific misconduct.



For the article “Sodium channels in the cytoplasm of Schwann cells” by J. M. Ritchie, J.A. Black, S. G. Waxman, and K. J. Angelides, which appeared in number 23, December 3, 1990, of *Proc Natl Acad Sci U S A* (87, 9290–9294), the undersigned authors would like to note the following: “This paper included immunocytochemical studies using antibody 7493. We interpreted immunostaining with antibody 7493 as providing information about sodium channel localization based on an immunological characterization of antibody 7493 carried out in the laboratory of K. J. Angelides. As reported in the *Federal Register* on March 12, 1999, based on the report of an investigation by the Baylor College of Medicine and on information obtained by the National Institutes of Health Office of Research Integrity (ORI) during its oversight review into allegations of scientific misconduct by Angelides, ORI, on March 10, 1997, found that Angelides falsified the description of the data in the corresponding text and legend of Fig. 1 of this paper and that his conduct constituted scientific misconduct. The Appeals Board of the Department of Health and Human Services (DAB) issued a decision on February 5, 1999, in which it affirmed the findings of ORI. Given the allegations of irregularity in the immunological characterization of antibody 7493 and the findings that ORI and DAB have made, we cannot stand behind the interpretation of results using this antibody. We therefore retract the immunocytochemical and immunoultrastructural results presented in this paper.” (J. M. Ritchie, J.A. Black, S. G. Waxman)

5. *Proc Natl Acad Sci U S A*. 1997;94:12732. **Retraction** submitted by co-author but not the author guilty of scientific misconduct.

An author (Hans-Jürgen Gruss) of the article “Tumor necrosis factor receptor-associated factor (TRAF)-1, TRAF-2, and TRAF-3 interact *in vivo* with the CD30 cytoplasmic domain; TRAF-2 mediates CD30-induced nuclear factor kappa B activation” by Stéphane Ansieau, Inka Scheffrahn, George Mosialos, Heike Brand, Justus Duyster, Kenneth Kaye, Josephine Harada, Bill Dougall, Gabi Hübinger, Elliott Kieff, Friedhelm Herrmann, Achim Leutz, and Hans-Jürgen Gruss, which appeared in number 24, November 26, 1996, of *Proc Natl Acad Sci U S A* (93, 14053–14058), has admitted scientific misconduct in misrepresenting data including Figs. 2C and 3. Because the experiments of Professor Gruss are a major part of this publication, I request that the paper be withdrawn. (Elliott Kieff)

6. *Proc Natl Acad Sci U S A*. Published online before print October 6, 2004, doi: 10.1073/pnas.0406725101. 2004;101:15271. **Retraction** submitted by editors.

For the article “Prevention of renovascular and cardiac pathophysiological changes in hypertension by angiotensin II type 1 receptor antisense gene therapy,” by Jeffrey R. Martens, Phyllis Y. Reaves, Di Lu, Michael J. Katovich, Kathleen H. Berecek, Sanford P. Bishop, Mohan K. Raizada, and Craig H. Gelband, which appeared in issue 5, March 3, 1998, of *Proc Natl Acad Sci*

*U S A* (95, 2664–2669), after an investigation by the Office of Research Integrity (ORI), Craig H. Gelband admitted to falsification of data, including Fig. 4 A and B. ORI determined that Dr. Gelband is solely responsible for the falsification. The editors, therefore, hereby retract the paper.

7. *BMJ*. 1998;316:1700. **Retraction** submitted by the editor.

The *BMJ* is retracting the paper by MH Williams and C Bowie (*BMJ*. 1993;306: 95–98) at the request of Dr Bowie. The General Medical Council found Dr Williams guilty of professional misconduct in February 1998 on charges which included research fraud. Dr Williams was responsible for the data collection of the original interview and examination survey in 1989 and the follow up telephone survey in 1990. Dr Bowie has been unable to verify that the data collection was carried out in an honest way. He did not scrutinise the data sheets at the time of the surveys; the data sheets of both surveys have been destroyed; and none of the 18 people still alive in Somerset and contacted by telephone six years later could remember the telephone interview.

8. *Gut*. 2004;53:774. **Retraction** submitted by the editor.

Due to an administrative error, one article has been published on two occasions. The journal would like to retract the paper by Lindsay et al in the July issue (*Gut*. 2003;52:981–987) as it is a replicated version of a paper by the same authors in the March issue (*Gut*. 2003;52:363–369). The journal apologizes for this error.

9. *Gut*. 2001;48:286. **Retraction** submitted by the editor.

*Gut* is retracting the paper by AK Banerjee and TJ Peters, “Experimental non-steroidal anti-inflammatory drug induced enteropathy in the rat—similarities to inflammatory bowel disease and effect of thromboxane synthetase inhibitors” (*Gut*. 1990;31:1358–1364) and the abstract AK Banerjee, R Sherwood, JA Rennie and TJ Peters, “Sulphasalazine reduces indomethacin induced changes in small intestinal permeability in man” (*Gut*. 1990;31:A593) at the request of Dr Banerjee. At the end of November 2000, the General Medical Council found Dr Banerjee guilty of serious professional misconduct and suspended him for 12 months. Both articles were deemed to contain information which was deliberately falsified.

10. *Biotechnol Adv*. 2004;22:619. **Retraction** submitted by the editor.

The article “Biotransformation of drugs by microbial cultures for predicting mammalian drug metabolism” (Srisilam K, Veeresham C. *Biotechnol Adv*. 2003;21:3–39) has been retracted at the request of the editors because the authors had infringed the normal professional ethical codes by plagiarizing another publication: “Microbial models for drug metabolism” (*Adv Biochem Eng Biotechnol*. 1999;63:69–218).



11. *Virus Res.* 2004;106:83. **Retraction** submitted by the publisher.

Retraction of “Nuclear factor kappa B (NFκB) dependent modulation of Epstein-Barr virus latent membrane protein 1 (LMP1) in epidermal growth factor receptor (EGFR) promoter activity” (Tao YG, Tan YN, Liu YP, Song X, Zeng L, Gu HH, Tang M, Li W, Yi W, Cao Y. *Virus Res.* 2004;104:61-70.) The publisher would like to announce that this paper has been retracted. A paper by the same group of authors containing essentially the same data and conclusions was published a short time earlier (*Cell Signal.* 2004;16:781-790). The authors have agreed to withdraw their paper from *Virus Research*.

12. *J Med Genet.* 2004;41:813. **Retraction** submitted by authors.

The authors of the following manuscript (Ninis VN, Kylynç MO, Kandemir M, Daöly E, Tolun. High Frequency of T9 and CFTR Mutations in Children with Idiopathic Bronchiectasis. *J Med Genet.* 2003;40:530-535) are retracting it because the polythymidine track genotype data are not correct. Recently the authors repeated the genotyping on 17 of the subjects to check whether the reported genotypes were correct and found out that they were not. At the time of submission of the manuscript, the authors were very confident of the data, since they had employed two independent methods for the genotyping of all subjects. However, subsequently the authors were prompted to recheck the results and have been unable to confirm them. The authors regret that we did not find out prior to publication.

13. *J Clin Invest.* 2003;112:1265. **Retraction** submitted by investigative panel.

The following manuscripts were part of an investigation in Germany. Herrmann F, Oster W, Meuer SC, Lindemann A, Mertelsmann RH. Interleukin 1 stimulates T lymphocytes to produce granulocyte-monocyte colony-stimulating factor. *J Clin Invest.* 1988;81:1415-1418.

Lindemann A, Riedel D, Oster W, Ziegler-Heitbrock HW, Mertelsmann R, Herrmann F. Granulocyte-macrophage colony-stimulating factor induces cytokine secretion by human polymorphonuclear leukocytes. *J Clin Invest.* 1989;83:1308-1312.

Oster W, Cicco NA, Klein H, Hirano T, Kishimoto T, Lindemann A, Mertelsmann RH, Herrmann F. Participation of the cytokines interleukin 6, tumor necrosis factor-alpha, and interleukin 1-beta secreted by acute myelogenous leukemia blasts in autocrine and paracrine leukemia growth control. *J Clin Invest.* 1989;84:451-457.

Nehls MC, Brenner DA, Gruss H-J, Dierbach H, Mertelsmann R, Herrmann F. Mithramycin selectively inhibits collagen- $\alpha$  1(I) gene expression in human fibroblast. *J Clin Invest.* 1993;92:2916-2921.



These manuscripts were evaluated as part of the Task Force Friedhelm Hermann, a group that investigated the findings published from the lab of Friedhelm Hermann for the Deutsche Forschungsgemeinschaft. The independent committee reviewed concerns related to the validity of the data associated with the above papers. As a result of the committee's findings, we are issuing a retraction of these papers. However, not all contributions by all authors of the papers were found to be fraudulent, and some authors have stated that their experimental contributions were legitimate.

14. *Nat Biotechnol.* 2004;22:601. **Retraction** submitted by all authors.

Retraction: Zeytun A, Jeromin A, Scalettar BA, Waldo GS, Bradbury ARM. Fluorobodies combine GFP fluorescence with the binding characteristics of antibodies. *Nat Biotechnol.* 2003;21(12):1473-1479. In this article, we concluded that inserting HCDR3 sequences derived from antibodies into a particular stable form of GFP created intrinsically fluorescent affinity reagents, which we termed "fluorobodies." We have recently realized that the strategy used to generate fluorobodies was flawed: the adaptor sequences reported contained additional nucleotides that introduced translational frameshifts at each HCDR3 insertion site. We expect this to have resulted in the creation of tripartite non-fluorescent "GFP-HCDR3 fragments" with the following structures: N-terminal in-frame GFP peptide/HCDR3 sequence/out-of-frame C-terminal GFP peptide.

Reexamination of the primary bacterial stocks of fluorobodies has revealed that these were not monoclonal, as originally assumed, but contained plasmid mixtures encoding both unmodified GFP and GFP-HCDR3 fragments. Segregation of these plasmids revealed that only colonies containing unmodified GFP genes were green. Following these discoveries, we have subsequently carried out immunofluorescence experiments with the remaining anti-tubulin fluorobody used in the published paper and obtained identical (microtubule-like) staining patterns, whereas GFP or anti-tubulin fluorobody prepared from frozen bacterial stocks gave nonspecific staining. With this exception, no original fluorobody protein preparations were available, and attempts to reproduce other results reported in the paper with fluorobodies expressed from frozen bacterial stocks were unsuccessful. We have reason to believe these stocks may have been compromised, and that the similarity of these stored stocks to the original stocks is questionable.

To determine whether correctly assembled fluorobodies would be functional, we have subsequently generated libraries of HCDR3s inserted at the single loop sites described in the paper, as well as into three (1-3) and four (1-4) loops simultaneously, within the context of a phage display vector. Only one of the single loop libraries (loop 3: in which 30% of clones had fluorescence greater than 5% of the GFP fluorescence, with a maximum of 12%) contained significant numbers of fluorescent clones; the rest were essentially nonfluorescent.





With the exception of the immunofluorescence data (produced by A.J. and B.A.S. using material prepared by A.Z.), all experiments were carried out by A.Z. in A.R.M.B.'s laboratory. We are presently unable to explain the biological activity described in the original publication. The possibility that this arose from noncovalent association of GFP with GFP-HCDR3 fragments in bacteria containing multiple plasmids is presently under investigation. In light of these findings, all authors agree that this study has not demonstrated the creation of fluorobodies as described, and consequently wish to unanimously retract the paper.

15. *Plant Cell*. 2004;16:785. **Retraction** submitted by all authors.

Jason W. Lilly, Jude E. Maul, and David B. Stern. The *Cblamydomonas reinhardtii* Organellar Genomes Respond Transcriptionally and Post-Transcriptionally to Abiotic Stimuli. *Plant Cell*. 2002;14:2681-2706. The authors of this article have requested that its publication be retracted from *The Plant Cell*. This follows a finding of the Boyce Thompson Institute for Plant Research that Dr Jason Lilly engaged in scientific misconduct, having falsified microarray data found in Figure 4 and the supplementary data set. The authors have further determined that a significant number of clones on the microarray were incorrectly annotated, and they have been unable to reproduce the increased accumulation of certain chloroplast mRNAs in response to sulfur deprivation. The authors wish to emphasize that Dr Lilly was found to be solely responsible for the scientific misconduct and misleading data associated with this publication. They deeply regret any inconvenience resulting from the publication of his data.

16. *N Engl J Med*. 2003;348:2137. **Expression of concern** submitted by editors.

In the issue of January 31, 2002, we published a study by Helmut Schiffl, MD, Susanne M. Lang, MD, and Rainald Fischer, MD (Daily hemodialysis and the outcome of acute renal failure. *N Engl J Med*. 2002;346:305-310). It has come to our attention, through communication with Klaus Peter, Dean of the Medical Faculty at Ludwig Maximilians University in Munich, Germany, that there is an ongoing investigation into potential scientific misconduct in the performance of this study. We will inform our readers of the outcome of this investigation when it is complete.

17. *Proc Natl Acad Sci U S A*. 2003;100:11816. **Expression of concern** submitted by editors.

Editorial Expression of Concern: The editors express a note of concern regarding the article "Preferential repair of ionizing radiation-induced damage in the transcribed strand of an active human gene is defective in Cockayne syndrome," by Steven A. Leadon and Priscilla K. Cooper, which appeared in issue 22, November 15, 1993, of *Proc Natl Acad Sci U S A* (90, 10499-10503). An ad hoc committee at the University of North Carolina at Chapel Hill (UNC) has concluded that the results published by Dr Steven A. Leadon, former



Professor of Radiation Oncology in the School of Medicine at UNC, which are based on his monoclonal antibody assays for transcription-coupled repair (TCR), should not be relied on unless independent verification exists.

After reviewing laboratory notebooks, the investigating committee could not confirm that equal amounts of DNA were loaded onto gel lanes that were then assayed for TCR. The committee concluded that the reported preferential repair of the transcribed DNA strand was not supported by available photographs of ethidium bromide-stained gels. The committee further concluded that Dr Leadon was solely responsible, at least for the last 7 years, for the step of the assay that determined the loading of the gel lanes. In addition, in the opinion of the UNC committee, this biased loading was deliberate and done without the knowledge of other scientists in his laboratory or his collaborators.

As a consequence of this investigation, the UNC committee requested that PNAS evaluate the results of the above-cited paper, which depends critically, but not exclusively, on Dr Leadon's TCR assay.

We have investigated the matter and are concerned about the validity of the results. We know of no independent verification of the data in the published figures. We therefore think it reasonable for the scientific community to view with extreme caution the results of these assays in the PNAS article. The editors emphasize that our skepticism does not extend to the validity of TCR, which has been amply corroborated by other experiments.

Dr Leadon does not concur with this assessment and note of concern. Although Dr Cooper cannot of her own knowledge dispute the stated concern with the TCR data, she attests that the conclusions from the paper are valid, based on subsequent work in several laboratories, including her own. (Nicholas R. Cozzarelli, Editor-in-Chief)

*(Authorship: Mary Scheetz took the lead in writing this section of the white paper on behalf of the CSE Policy Committee. Members of the Policy Committee and the CSE Board of Directors reviewed and commented on it. This section was formally approved by the CSE Board of Directors on September 13, 2006.)*

## **3.6 Handling Third-Party Inquiries About Scientific Misconduct**

### **3.6.1 Media**

When a case of scientific misconduct has achieved a certain level of notoriety, members of the media will sometimes contact an editor and seek information about the case. Most editors find it easier to respond to such inquiries with a statement that they do not discuss such cases. If the inquiry concerns a published paper, the editor often will indicate that they are investigating the matter and are awaiting the results of the investigation. Often the media will attempt to determine possible outcomes by proposing various hypothetical



scenarios to the journal editor. Such lines of inquiry can be deflected by truthfully stating that the editor cannot respond to hypothetical scenarios because each case has unique facts and circumstances.

### 3.6.2 Legal Counsel

Legal counsel typically contact editors through a letter seeking redress, information, or action. An editor may receive a letter from counsel seeking to redress a perceived wrong inflicted on his or her client, such as a demand that a paper be retracted or a request that an author's name be added to the paper. Further, legal counsel may allege that the journal did not follow its own guidelines regarding review or publication. However, it is the judgment of the editor that prevails. In at least one case, a lawyer demanded that the journal conduct an investigation of perceived misconduct by a scientist who had published in the journal. Editors are within their prerogative to indicate that the institution employing the scientist has primary responsibility for conducting such investigations. Some editors prefer to advise counsel of that fact rather than directly notifying the author's institution and being labeled the whistleblower.

Other counsel seek disclosure of information for a case they are working on, such as the identities of the peer reviewers. Despite the demands of these sternly written letters, most courts have respected the anonymity of reviewers. Accordingly, editors should resist providing such information until ordered by a court to do so. Some journals consider retaining their own counsel a cost of doing business. When these journals receive a letter from a lawyer, the editor refers the matter directly to the journal's own counsel without taking further action. For those journals that do not have dedicated counsel, developing a policy for responding to such inquiries often is more cost-effective than attempting to resist a motion to compel a certain action. A journal's counsel can explain to opposing counsel the weakness of their client's position without resort to expensive litigation.

### 3.6.3 Federal Agencies

For a variety of reasons, it is rare for a federal agency to approach a journal editor and ask for assistance in investigating allegations of misconduct. First, journals typically are not recipients of federal funds and thus agencies do not have jurisdiction over their affairs. Second, journals cannot typically impose a sanction against an author found to be guilty of misconduct, beyond retraction or declining to accept future submissions. Finally, as noted above, the institutions that employ scientists have primary responsibility for conducting investigations into allegations of misconduct.

*(Authorship: Debra Parrish and Martin Blume took the lead in writing this section of the white paper on behalf of the CSE Policy Committee. Members of the Policy Committee and the CSE Board of Directors reviewed and commented on it. This section was formally approved by the CSE Board of Directors on September 13, 2006.)*

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