CSE's White Paper on Promoting Integrity in Scientific Journal Publications, 2009 Update

Editorial Policy Committee (2008–2009)

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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/services/policies.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 to achieve that goal. We first wrote this white paper in 2006. For the 2009 Update, we substantially revised and updated each section; reorganized the Authorship and Author Responsibilities section; included emerging issues, such as dual use research and cell line authentication; revised information on clinical trial registration and open access; and provided up-to-date examples of corrections, retractions, and expressions of concern.

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 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. Where 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. Please help us to keep this living document current 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 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 Editorial Policy Committee. Heather Goodell revised this section for the 2009 Update. Members of the Editorial 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 March 29, 2009.)

2.0 ROLES AND RESPONSIBILITIES IN PUBLISHING

2.1 Editor Roles and Responsibilities

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

Editor Responsibilities toward Authors

- 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 for *all* involved in the publication process, including editors, staff (e.g., editorial and sales), authors, and reviewers
- Protecting the confidentiality of every author's work
- Establishing a system for effective and rapid peer review (see section 2.3)
- Making editorial decisions with reasonable speed and communicating them in a clear and constructive manner
- Establishing clear guidelines for authors regarding acceptable practices for sharing experimental materials and information, particularly those required to replicate the research, before and after publication
- Establishing a procedure for reconsidering editorial decisions (see section 2.1.9)
- Describing, implementing, and regularly reviewing policies for handling ethical issues and allegations or findings of misconduct by authors (see sections 2.1.10 and 3.0)
- Informing authors of solicited manuscripts that the submission will be evaluated according to the journal's standard procedures or outlining the decision-making process if it differs from those procedures
- Developing mechanisms to ensure timely publication of accepted manuscripts (see section 2.1.6)
- Clearly communicating all other editorial policies and standards

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 conducted according to the protocol approved by the relevant institutional review boards or ethics committees for human (including human cells or tissues) or animal experiments and that all human subjects provided appropriate informed consent.
- Describe in the manuscript methods section how cultured cell lines were authenticated.
- 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 examples, see the statements from the Federation of American Societies for Experimental Biology,[1] the Canadian Council on Animal Care,[2] and, for links to other informational sites, the University of California, San Francisco.[3]

- 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 as authors and identify other support (e.g., statistical analysis or writers), with the contributor's approval, in the acknowledgment section. In addition, some journals have a requirement for original research (sometimes called a guarantor policy) that at least one author who had full access to all the data takes responsibility for its integrity and the accuracy of the data analysis. *JAMA* publishes these statements in the acknowledgment section. A description can be found in the *JAMA* Instructions for Authors.[4]
- Reveal any potential conflicts of interest of each author either in the cover letter, manuscript, or disclosure form,[5] in accordance with the journal's policy.
- Include (usually written) permission from each individual identified as a source of 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 (e.g., actual data that was summarized in the manuscript) to the editor when requested.
- Share data or materials needed by other scientists to replicate the experiment. As an example, the Information for Authors of the *Proceedings of the National Academy of Sciences (PNAS)*[6] 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 copyrighted content (e.g., figures and tables) in the submitted manuscript, if applicable.[7]

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[1] Federation of American Societies for Experimental Biology. Animals in research and education. Available at: http://opa.faseb.org/pages/PolicyIssues/animalresearch.htm (Accessed March 28, 2009).

[2] Canadian Council on Animal Care. Terms of reference for animal care committees. Available at: http://www.ccac.ca/en/CCAC_Programs/Guidelines_Policies/POLICIES/TERMS00E.HTM (Accessed March 28, 2009).

[3] University of California, San Francisco, additional research links. Available at: http://www.research.ucsf.edu/arc/index.asp (Accessed March 28, 2009).

[4] *JAMA* Instructions for authors. Available at: http://jama.ama-assn.org/misc/ifora.dtl#DataAccessandResponsibilityin our I (Accessed March 28, 2009).

[5] A sample disclosure form can be found at: http://jama.ama-assn.org/cgi/data/295/1/103/DC1/1 (Accessed March 28, 2009).

[6] *Proceedings of the National Academy of Sciences (PNAS)* Information for authors. Available at: (http://www.pnas.org/misc/iforc.shtml (Accessed March 28, 2009).

[7] An example of information commonly required for permission to reuse copyrighted material can be found at: http://www.nutrition.org/publications/guidelines-and-policies/permissions/ (Accessed March 28, 2009).

- Provide written permission from any potentially identifiable individuals referred to or shown in photographs in the manuscript.
- Copyright transfer statement[8] or licensing agreement.[9]

Some journals may also request or require adherence to the following trial registration or reporting guidelines:

- Registration information for clinical trials (See section 2.2.6).[10,11]
- Adherence to the CONSORT statement,[12] which helps standardize reports of randomized trials.
- The use of the STARD flow diagram and checklist[13] for reporting diagnostic tests.
- Compliance with MOOSE guidelines[14] for reporting meta-analyses and systematic reviews of observational studies.
- Adherence to STROBE checklists[15] for the reporting cohort, case-control, and cross-sectional observational studies.
- Adherence to QUOROM guidelines[16] for reporting meta-analyses and systematic reviews of randomized controlled trials.
- Adherence to the MIAME standards[17] for reporting microarray experiments.

A resource that provides information about many of the reporting guidelines is the EQUATOR network.[18]

Peer Review

Editors are 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 ensure manuscript quality. However, editors may sometimes reject manuscripts without external peer review to make the best use of their resources. Reasons for this practice are usually that the manuscript is outside the scope of the journal, does not meet the journal's quality standards or is of limited scientific merit, or lacks originality or novel information.

Reviewers are chosen by the editors. The amount of anonymity in the peer review process varies. Some journals attempt to mask the identities of both the authors and reviewers (double masked); however, although masked, the

[8] A sample copyright transfer agreement is available at: http://circres.ahajournals.org/misc/AHA-CTA08-2008.pdf (Accessed March 28, 2009).

[9] A sample licensing agreement is available at: http://www.nature.com/nbt/pdf/nbt_license.pdf (Accessed March 28, 2009).

[10] Some guidelines for registering clinical trials can be found at: http://jama.ama-assn.org/cgi/content/full/292/11/1363 (Accessed March 28, 2009).

[11] The Council of Science Editors' endorsement statement of the ICMJE policy regarding clinical trial registration is available at: http://www.councilscienceeditors.org/editorial_policies/endorsementofprinciples.cfm (Accessed March 28, 2009).

[12] The CONSORT statement. Available at: http://www.consort-statement.org (Accessed March 28, 2009).

[13] STARD flow diagram. Available at: http://www.clinchem.org/cgi/content/full/49/1/1 (Accessed March 28, 2009).

[14] MOOSE guidelines. Available at: http://jama.ama-assn.org/cgi/content/full/283/15/2008 (Accessed March 28, 2009).

[15] STROBE statement. Available at: http://www.strobe-statement.org/ (Accessed March 28, 2009).

[16] QUORUM guidelines. Available at: http://www.consort-statement.org/mod_product/uploads/QUOROM%20Statement%201999.pdf (Accessed March 28, 2009).

[17] MIAME standards. Available at: http://www.mged.org/Workgroups/MIAME/miame_1.1.html (Accessed March 28, 2009).

[18] The EQUATOR network. Available at: http://www.equator-network.org/ (Accessed March 28, 2009).

identity of the author(s) may be known by the reviewers based on the area of research. Some journals follow the practice of keeping reviewer identities anonymous to the authors (single masked). Alternatively, some journals give reviewers the option to reveal their names, and a few journals provide authors with the names of all reviewers associated with the manuscript.

Peer review is usually a gift of uncompensated time from scientists to whom time is a precious commodity. Therefore, it is important for editors to clearly define the responsibilities of these individuals and to implement processes that streamline the peer review process as much as possible (see section 2.3 for more on reviewer responsibilities).

Editor Responsibilities toward Reviewers

- Assigning papers for review appropriate to each reviewer's area 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 to take advantage of the knowledge they gained by reviewing it before publication
- 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 reasonable frequency that does not overtax any one reviewer
- Finding ways to recognize the contributions 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.

Editor Responsibilities toward Readers and the Scientific Community

- Evaluating all manuscripts considered for publication to make certain that each 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 interested readers may pursue further discourse
- Identifying individual and group authorship clearly and developing processes to ensure that authorship criteria are met to the best of the editor's 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. Some journals ask that one author be the guarantor and take responsibility for the work as a whole

- Maintaining the journal's internal integrity (e.g., correcting errors; clearly identifying and differentiating types of content, such as reports of original data, opinion pieces [e.g., editorials and letters to the editor], corrections/errata, retractions, supplemental data, and promotional material or advertising; and identifying published material with proper references)
- Disclosing sources (e.g., authorship, journal ownership, and funding)
- Creating mechanisms to determine if the journal is providing what readers need and want (e.g., 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 (freely available versus subscriber only)

Journal Ownership

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

Editor Responsibilities toward Journal Owners/Publishers

- Conducting peer review of submitted manuscripts
- 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-upon mission, publication practices, and schedule

Meeting all obligations, which sometimes compete against 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.

Responsibilities of Editors toward the Public

Many responsibilities of editors toward the public are carried out through the mechanisms established for the processes and constituencies mentioned above. Editors' roles have benefited society in many ways, from the quality-control measures taken when considering manuscripts for publication to requiring authors to abide by standards that would advance science and deposit information into freely available public databases as a condition of publication (e.g., data sharing). Editors are regularly taking steps to see that the outcomes of the scientific enterprise benefit the public. This includes identifying dual use research, which is research that can be misused to harm the public or its well-being.

Dual Use Research

One additional area that has emerged with advances in science, technology, and global exchange of information is consideration of "dual use research." This is research with a legitimate scientific purpose that may be misused to pose a threat to public health and/or national security. As defined by the United States National Science Advisory

Board for Biosecurity (NSABB), dual use research of concern (DURC) is a subset of dual use research "that, based on current understanding, can be reasonably anticipated to provide knowledge, products, or technologies that could be directly misapplied by others to pose a threat to public health and safety, agriculture, plants, animals, the environment, and materiel."[19] Examples include knowledge, products, or technologies that could be misapplied to create or enhance harmful consequences of biological agents or toxins, disrupt immunity of vaccines, increase transmission of harmful substances, or alter biological agents and toxins to make them resistant to clinical or agricultural prophylactic or therapeutic interventions, or conversely to enhance the susceptibility of a host population to harm.

Everyone has a stake in the responsible management of DURC, but especially individual researchers, institutions and institutional groups (e.g., institutional biosafety committees), funding agencies, scientific societies, government/regulatory bodies, journal editors, and the global scientific community. In the United States, the National Policy on the Transfer of Scientific, Technical, and Engineering Information, issued in 1985 (National Security Decision Directive-189),[20] states that, to the maximum extent possible, federally funded fundamental research that is unclassified will not have government-imposed restrictions on its conduct or reporting. More recent legislation, such as the USA PATRIOT Act of 2001 (P.L. 107-56)[21] and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (P.L. 107-188, H.R. 3448), takes additional steps intended to prevent bioterrorism, including the establishment of a national database of potentially dangerous pathogens and imposition of safety and security requirements on facilities and individuals with access to them.

Identification and consideration of DURC throughout the research continuum prior to submission of manuscripts for publication is an important early step. However, while journal editors do not have sole responsibility for the management of DURC, inevitably, editors will be faced with submissions that could be considered DURC and the challenges that come with handling them. Considering the risks and benefits of publishing DURC is a task in which many editors have no experience. Identifying DURC is subjective, and it is difficult for even the most knowledgeable editors and scientists to manage submissions that provide legitimate scientific contributions without censoring their communication because of potential harmful use. In 2003, a group of editors published the "Statement on Scientific Publication and Security." This document states that there may be times when it is appropriate to "encourage investigators to communicate results of research in ways that maximize public benefits and minimize risks of misuse." The signatories of this statement believe there may be rare cases in which some information needed to reproduce the experiment should be eliminated or the manuscript itself should not be published. Editors who may potentially receive DURC submissions should consider establishing best practices for processing these manuscripts.

In 2003, the "Statement on Scientific Publication and Security"[22] was published by a group of editors simultaneously in *Science*, *Proceedings of the National Academy of Sciences*, *Nature*, and the American Society for Microbiology journals. This statement recognizes the challenge of dual use research and documents the commitment of journal

[19] National Science Advisory Board for Biosecurity. Proposed framework for the oversight of dual use life sciences research: strategies for minimizing the potential misuse of research information, June 2007. Available at: http://oba.od.nih.gov/biosecurity/pdf/Framework%20for%20transmittal%200807_Sept07.pdf (Accessed March 28, 2009).

[20] National Security Decision Directives. National policy on the transfer of scientific, technical, and engineering information. Available at: http://www.fas.org/irp/offdocs/nsdd/nsdd-189.htm (Accessed March 28, 2009).

[21] USA PATRIOT Act of 2001. Available at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_public_laws&docid=f:publ056.107.pdf (Accessed March 28, 2009).

[22] Journal Editors and Authors Group. Statement on scientific publication and security. *Science* 2003;299(5610):1149. Available at: http://www.sciencemag.org/cgi/content/summary/299/5610/1149 (Accessed March 28, 2009).

editors and authors toward responsibly and effectively balancing the need for public safety with the requirements of transparently reporting scientific results. There may be times when it is appropriate to "encourage investigators to communicate results of research in ways that maximize public benefits and minimize risks of misuse." In rare cases, some information needed to reproduce the experiment should be eliminated or the manuscript itself should not be published.

The NSABB and organizations around the world have entered into dialogues with all stakeholders to find ways to ensure that science continues to be done and communicated in an unfettered way, while being mindful of and minimizing the risks and consequences of misuse. Tools and information on this topic are being built and shared by the global community.

Editors can educate journal boards, reviewers, and authors; establish screening methods to recognize DURC; obtain reviews of these manuscripts from individuals with technical and security expertise; and create an ongoing network to share experiences and further refine ways for managing DURC.

Editors should develop guidelines and procedures to allow the scientific evaluation as well as the evaluation of the possible risk of communicating information with dual use potential. Additional information on what to consider when evaluating a manuscript with potential dual use can be found in the report titled, Biotechnology Research in an Age of Terrorism.[23]

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 the editor and the 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, including the degree of control regarding editorial content, acceptance and publication, and advertising content (a sample job description can be found in the Appendix to this section)
- 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-upon 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

[23] Committee on Research Standards and Practices to Prevent the Destructive Application of Biotechnology, National Research Council. Biotechnology Research in an Age of Terrorism. Available at: http://www.nap.edu/catalog.php?record_id=10827 (Accessed March 28, 2009).

2.1.2 Confidentiality

Editors and the publication staff should keep all information about a submitted manuscript confidential, sharing it only with those involved in the evaluation, review, and publication processes.

Editors should consider adding a confidentiality notice to *all* correspondence, including reviewer forms, to serve as a reminder to authors, editors, and reviewers.

To minimize 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. Records and retention schedules, such as how long to keep published manuscripts and associated correspondence or rejected manuscripts and associated correspondence, should be documented in writing and reviewed on a regular basis.

Journals may receive subpoenas for information about manuscripts. Legal counsel is advised in this scenario. Formal subpoenas can be issued only by a regulatory agency or court of competent jurisdiction. Formal inquiries from law firms, for example, are probably best to politely decline, citing confidentiality. Generally, editors should resist revealing confidential information when served a subpoena unless advised to do so by legal counsel. Not only is the requested information usually confidential, but often uncovering ALL information (for which lawyers are trained to ask) can be time-consuming, interrupt normal business, and be expensive. Citing, for example, the Avoidance of Undue Burden or Expense Under Rule 45(c)(1) of the Federal Rules of Civil Procedure may be useful.[24]

Confidential information should not be used for an editor's 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 on such cases until they are satisfactorily resolved.

Generally, editors of journals with embargo policies should enforce them to encourage the confidentiality of publication content until the embargo release date, unless the editor is authorized by the copyright owner or required by law to disclose the information. The copyright owner is often the journal owner—usually the society or publisher—but may be 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 a *JAMA* editorial[25] (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.

[24] Parrish, DM, Bruns, DE. US legal principles and confidentiality of the peer review process. *JAMA* 2002;287(21):2839–2841.

[25] Fontanarosa PB, DeAngelis. The importance of the journal embargo. *JAMA* 2002;288(6):748–750. Available at: http://jama.ama-assn.org/cgi/content/full/288/6/748 (Accessed March 28, 2009).

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. Enforcement of these policies must also be considered. Practices to handle violations of the journal's conflict of interest policy should be stated in writing, regularly reviewed, and carried out consistently.

One 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.

- **Financial conflicts.** 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). The most evident type of potential financial conflict of interest arises when an individual or organization may benefit financially from a decision to publish or to reject a manuscript. 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 by 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 (e.g., consulting fees, honoraria, or 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; therefore, they must be regarded as a potential conflict of interest and 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.

- **Nonfinancial conflicts.** Nonfinancial conflicts of interest include personal, political, academic, and religious conflicts. Editors and reviewers should avoid making decisions about manuscripts that may conflict with their own interests. Decisions in these cases should be delegated to other editors, members of the Publications Oversight Committee, or assigned to other reviewers (see section 2.3.2 for information on the ethical responsibilities of reviewers). Editors should submit their own manuscripts to the journal only if masking of the review process can be ensured (e.g., anonymity of the peer reviewers and lack of access to records of their own manuscript). Examples of potential nonfinancial conflicts that should be avoided or disclosed are listed below.
  - A reviewer evaluating a manuscript reporting research results similar to results he or she is preparing to submit for publication might be tempted to delay the review until his or her manuscript is

accepted or might 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

Explanation and enforcement of authorship disclosure. It is the editors' responsibility to establish the authorship criteria guidelines for their journals. Many biomedical journals operate according to the standards established by the International Committee of Medical Journal Editors (ICMJE).[26] 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[27] suggests that, among 3 highly regarded biomedical publications, the effectiveness of authorship and contributorship policies varies.

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 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 manufacture or sale of that product. Others prefer that editorials or review articles not 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 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

[26] International Committee of Medical Journal Editors (ICMJE). Uniform requirements for manuscripts submitted to biomedical journals. Available at: http://www.icmje.org (Accessed March 28, 2009).

[27] Bates T, Anic A, Marusic M, Marusic A. Authorship criteria and disclosure of contributions. *JAMA*. 2004;292:86–88.

scientific merit is assessed. Those journals that request and publish specific conflict of interest information are more likely to avoid inconsistent handling, but they may unnecessarily use editorial space for this purpose. While some journals ask that all potential financial conflicts be disclosed, others ask authors to identify only those that exceed a certain monetary amount.

The ICMJE[28] states: "Editors should publish this information if they believe it is important in judging the manuscript." This approach gives the editor the discretion to decide whether the potential conflict is significant enough to reveal. Examples of disclosure forms and actual disclosures can be found in the *Annals of Internal Medicine*,[29] the American Society of Hematology's journal *Blood*,[30] and the American Academy of Neurology's journal *Neurology*.[31]

- **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 conflict of interest disclosure form for both reviewers and authors, as 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 that 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 request potential editors to identify service on other publication boards and may consider an editor's role in the editorial and financial decisions of a competing publication inappropriate.

The editor-in-chief or principal editor should ensure that the journal's editors and editorial board are identified in the journal masthead; receive the necessary training and oversight to adequately perform editorial functions; and actively perform 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 time 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.

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[28] International Committee of Medical Journal Editors (ICMJE). Uniform requirements for manuscripts submitted to biomedical journals. II.D. Conflicts of interest. Available at: http://www.icmje.org/index.html#conflicts (Accessed March 28, 2009).

[29] *Annals of Internal Medicine* conflict of interest information available at: http://www.annals.org/shared/author_info.shtml#authorsprofessional (Accessed March 28, 2009).

[30] *Blood* conflict of interest form. Available at: http://bloodjournal.hematologylibrary.org/forms/copyright_transfer.dtl (Accessed March 28, 2009).

[31] *Neurology* disclosure agreement. Available at: http://www.neurology.org/misc/DisclosureFormDummyForRef.pdf (Accessed March 28, 2009).

Some journals publish annual editorial audits,[32] which include the total number of manuscripts submitted, acceptance rates of solicited and unsolicited manuscripts, and the average manuscript turnaround time. 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 (e.g., 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 (See 2.2). Authorship disputes persist despite the current common efforts to make authorship or contributorship transparent. 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 editorial practices should be in place to consistently handle authorship disputes. For example, an individual may contact the editor with a complaint about not being included in the author byline of a submitted manuscript despite having met authorship criteria. In this case, the editor should query the corresponding author regarding the claim. Depending on the response, the journal may need to turn the investigation of the complaint over to the institution(s) where the work reported in the manuscript was done. In most cases, the journal will not have enough information to make a judgment regarding the allegation. Consideration of the manuscript may have to be postponed pending resolution of the complaint. Authorship abuses may be driven by some factors that are beyond the role of the editor (tenure decisions, funding, awards, or competition among authors). Editors, however, should collaborate with research institutions and other organizations to determine why authorship disputes continue to arise and to work toward solutions.

[32] An example of an editorial audit is available at: http://www.conbio.org/Publications/Newsletter/Archives/2008-8-August/newsl013.cfm (Accessed March 28, 2009).

2.1.9 Considering Appeals for 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, although it is not easy to explain to an author that the research report in his or her manuscript does not compete with the many others under consideration.

- Determine whether the decision was clearly explained to the author and whether it 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 section 3.0)

Concerns of 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. Journals 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 failure 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 Editorial Policy Committee. Diane Scott-Lichter and Deborah Polly revised this section for the 2009 Update. Members of the Editorial 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 March 29, 2009.)

2.1.11 Resources and Case Studies

American Chemical Society. Ethical guidelines to publication of chemical research. Available at: http://pubs.acs.org/userimages/ContentEditor/1218054468605/ethics.pdf (Accessed March 28, 2009).

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Annals of Internal Medicine. Authors' professional and ethical responsibilities. Available at: http://www.annals.org/shared/author_info.shtml#authorsprofessional (Accessed March 28, 2009).

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DeAngelis CD, Drazen JM, Frizelle FA, et al. Clinical trial registration: a statement from the International Committee of Medical Journal Editors. *JAMA*. 2004;292:1363–1364.

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International Committee of Medical Journal Editors (ICMJE). Uniform requirements for manuscripts submitted to biomedical journals. II.D. Conflicts of interest. Available at: http://www.icmje.org/#conflicts (Accessed March 28, 2009).

JAMA. Authorship responsibility, financial disclosure, copyright transfer, and acknowledgment. Available at: http://jama.ama-assn.org/cgi/data/292/1/112/DC1/1 (Accessed March 28, 2009).

Neurology. Authorship, non-financial, and financial disclosure form. Available at: http://www.neurology.org/misc/DisclosureFormDummyForRef.pdf (Accessed March 28, 2009).

Society for Conservation Biology. Conservation Biology Editors' Report: turnaround time. Available at: http://www.conbio.org/Publications/Newsletter/Archives/1997-8-August/aug97008.cfm#A14 (Accessed March 28, 2009).

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University of California, San Francisco (UCSF) Office of Research. Animal research and care. Available at: http://www.research.ucsf.edu/arc/index.asp (Accessed March 28, 2009).

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 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 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 (e.g., Instructions for Authors, Instructions for 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 potential successors to the Society.

2.2 Authorship and Author Responsibilities

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

Many journals provide guidelines for authorship in their Instructions for Authors, as do many professional organizations in their statements on ethics. Although the following guidelines on authorship and contributorship were formulated in the context of biomedicine, many of their underlying principles are applicable to all areas of science.

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[33] 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; it also lists the names of collaborators if they are listed in the Acknowledgments.
- Acquisition of funding, collection of data, or general supervision of the research group, alone, does not constitute 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.[33]

During the 1990s, this model came under scrutiny because the number of individuals and breadth of contributions involved in clinical studies increased and because authors failed to make adequate disclosures.[34,35] The perceived inadequacies in the ICMJE model led some to suggest a complementary model that departed from the more

[33] International Committee of Medical Journal Editors (ICMJE). Uniform requirements for manuscripts submitted to biomedical journals. II.A. Authorship and contributorship. Available at: http://www.icmje.org/#author (Accessed March 28, 2009).

[34] Rennie D, Yank V, Emmanuel L. When authorship fails: a proposal to make contributors accountable. *JAMA*. 1997;278:579–585.

[35] Yank V, Rennie D. Disclosure of researcher contributions: a study of original research articles in The Lancet. *Ann Intern Med*. 1999;130:661–670.

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.[34]

This model of "contributorship" has been adopted by a number of major biomedical journals.[36] The general aim of contributorship disclosure is to have authors describe, on the basis of a contributor taxonomy created by journal editors, exactly what each author did during the course of the study from its inception to publication, such as obtaining funding for the study; recruiting subjects; coordinating, collecting, and analyzing the data; and writing and revising the manuscript.[35] Under this model, authors are also expected to designate their functional role within the group (e.g., principal investigator, coinvestigator, statistician, contributing author).[35] It is argued that this additional layer of disclosure contributes to greater transparency on the part of authors.[36]

2.2.2 Authorship and Contributorship Criteria

The purpose of contributorship disclosures is to have each author and/or contributor personally affirm his or her role, to disclose publicly to readers what each author did,[36] and to gain from authors what Jerome Kassirer has described as "public responsibility for [article] content."[37] While the ICMJE criteria provide guidance about the types of contributions that characterize authors, it is ultimately the role of researchers themselves and not the editors to decide which individuals have contributed sufficiently to earn the designation "author." Individuals who have made less substantial contributions should be identified in the Acknowledgments.

What authorship problems are editors specifically trying to identify and address? A range of inappropriate types of authorship have been described, including guest authorship, honorary or gift authorship, and ghost authorship.[36]

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 contributions to the study, so this person meets none of the criteria for authorship.

Honorary or gift authorship. Honorary or gift authorship has been defined as authorship based solely on a tenuous affiliation with a study. A salient example would be "authorship" based on one's position as the head of a department in which the study took place.

Ghost authorship. Ghost authors participate in the research, data analysis, and/or writing of a manuscript but are not named or disclosed in the author byline or Acknowledgments. Examples of ghost authors include undisclosed contributors who are employees of pharmaceutical or device companies, medical writers, marketing and public relations writers, and junior staff writing for elected or appointed officials.[38] Any person who makes a substantial contribution to a manuscript should be listed in the author byline, if appropriate, or in the Acknowledgments, along with the individuals' institutional affiliations, if relevant.[39]

Anonymous Authorship. Because authorship should be transparent and requires public accountability, it is not appropriate to use pseudonyms or to publish scientific reports anonymously. In extremely rare cases, when the author can make a credible claim that attaching his or her name to the document could cause serious hardship (e.g., threat to personal safety or loss of employment), a journal editor may decide to publish anonymous content.

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[36] 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.

[37] Kassirer JP. Authorship criteria. *Science*. 1995;268:785–786.

[38] Flanagin A, Rennie D. Acknowledging ghosts. *JAMA*. 1995;273(1):73.

[39] American Medical Association Manual of Style: A Guide for Authors and Editors, 10th edition. Oxford: Oxford University Press; 2007:128–140.

Other categories of authorship that may be acceptable in certain circumstances include group authorship and the inclusion of deceased or incapacitated authors.

Group Authorship. Group authorship[40] may be appropriate when a group of researchers has collaborated on a project, such as a multicenter trial, a consensus document, or an expert panel. Because it can be inaccurate and impossible to list all collaborators (some would not meet basic ICMJE 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:[39]

- 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.

Deceased or Incapacitated 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.[39]

2.2.3 Acknowledgments

In an Acknowledgments section, authors may wish to include the names and contributions of those whose involvement in a study did not qualify them for authorship or, because of journal policy on the number of authors in the author byline, cannot be included in the author byline. Authors should have each person listed in the acknowledgment sign a disclosure form or other statement acknowledging that they agree to have their names appear.

2.2.4 Order of Authors

The order of authors in the byline is a collective decision of the authors or study group. Disagreements about author order should be resolved by the authors before the article is submitted for publication. Disputes that arise after submission could delay or prevent publication. Authors should not expect editors to become embroiled in disputes among authors over name placement in the byline.

Much has been written about the meaning of each place in the byline listing, particularly among the first 6 authors.[39] Some journals specify how many authors they will accept in the author byline, which can range between 3 and 25 authors.

2.2.5 Changes to the Author Byline

Any changes the authors wish to make to the author byline after the initial submission of a manuscript should be made in writing and the document should be signed by all authors, including those being added or removed. The new author list should be stated directly along with a justification for the change.

2.2.6 Author Responsibilities

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

[40] The CSE recommendations for group-author articles in scientific journals and bibliometric databases. Available at: http://www.councilofscienceeditors.org/publications/group_authorship.pdf (Accessed March 28, 2009).

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 section 2.6 on responsibilities to the media).

Originality. The authors should provide a statement attesting to the originality of the study they have submitted for consideration. Originality is crucial, 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, and abstracts) related to the study under consideration.

Disclosures. 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, and financial and conflict of interest disclosures. Some journals also require statements on the regulatory status of any drugs or devices used in the study.[41] Authors should expect editors to publish all relevant disclosures with their accepted manuscript.

Many journals require authors to disclose sources of funding for the study they wish to report. 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 the research, analysis, or reporting. Some journals stipulate that authors disclose financial relationships in dollar amounts and set specific dollar thresholds. Items to be disclosed include employment, consultancies, stock ownership, honoraria, expert testimony, and patents.[42]

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.[43]

Copyright Assignment. In medical publishing, authors are usually expected to assign copyright to the journal publishing their study. Assignment of copyright is a legal document in which the authors assign certain rights to the publisher. Alternatively, some journals may use a licensing agreement. Although individual arrangements vary, these agreements generally allow the authors to retain certain rights to the material. In either case, the content in question must be 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 must avoid duplicate publication, which 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 may violate copyright and could be an indication that the study contributes only marginally to the literature.

Permissions. Authors frequently wish to reuse previously published images and other copyrighted material. It is the author's responsibility to follow journal or publisher guidelines to reuse any copyrighted material and provide proper attribution. This includes the author's own work if the copyright was ever transferred to a publisher or journal. Authors should contact the journal or publisher of the source material or consult the "permissions" information that

[41] An example of a regulatory status statement is available at: http://www.elsevier.com/framework_products/promis_misc/623354dsca.pdf (Accessed March 28, 2009).

[42] Examples of disclosure forms are available at: http://authors.nejm.org/help/disclosrev.pdf (Accessed March 28, 2009) and http://www.jbjs.org/pdf/conflict.pdf (Accessed March 28, 2009).

[43] Examples of contributorship forms are available at: http://www.annals.org/shared/AuthorsForm.pdf (Accessed March 28, 2009) and http://www.springer.com/cda/content/document/cda_downloaddocument/ABJSCTAwSigLines.pdf?SGWID=0-0-45-495798-p173705903 (Accessed March 28, 2009).

can be found on many of their web sites. Permission should be granted in writing and the authors should retain this documentation. The editor may request a copy of this notification as well.

Multiple Submissions. 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. Authors who do not follow this standard may find that editors reject their papers as a violation of policy. In addition, this practice can be a violation of copyright.

If authors want to submit their article to another journal while it is under consideration elsewhere, then they must send formal notification to the editor of the journal in which it is under consideration, requesting that their study be withdrawn from further consideration (see section 3.1.3). 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 manuscript has been withdrawn from future consideration. On receipt of notification from the journal acknowledging the withdrawal, the authors may submit their manuscript elsewhere. They should retain a copy of the notification.

Registration of Clinical Trials. ICMJE's member journals[44] and many others require that to be considered for publication, any prospective, interventional clinical research study must have been appropriately recorded in an approved trial registry before enrollment of the first subject.[45,46] The goal of this policy is to promote the public availability of a comprehensive database of clinical trials. Registry is undertaken by trial investigators or sponsors (see section 2.4 on sponsor roles and responsibilities). The ICMJE recommends that journals publish the trial registration number at the end of the abstract and that authors specify the registration number the first time they use a trial acronym in a manuscript.[46] Before the start of a study, the authors should consider whether the journals to which they may want to submit their study report have adopted this policy.

The ICMJE accepts registration in the following registries:

- Australian New Zealand Clinical Trial Registry[47]
- ClinicalTrials.gov[48]
- International Standard Randomised Controlled Trial Number (ISRCTN) Register[49]
- University hospital Medical Information Network Clinical Trials Registry (UMIN-CTR)[50]
- Netherlands Trial Register[51]

[44] Journals that have requested inclusion on the list of publications that follow the ICMJE's Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Available at: http://www.icmje.org/jrnlist.html (Accessed March 28, 2009).

[45] International Committee of Medical Journal Editors (ICMJE). Is this clinical trial fully registered? A statement from the International Committee of Medical Journal Editors. May 2005. Available at http://www.icmje.org/clin_trialup.htm (Accessed March 28, 2009).

[46] International Committee of Medical Journal Editors (ICMJE). Obligation to register clinical trials. Available at: http://www.icmje.org/index.html#clin_trials (Accessed March 28, 2009).

[47] Australian New Zealand Clinical Trial Registry. Available at: http://www.anzctr.org.au/Survey/UserQuestion.aspx (Accessed March 28, 2009).

[48] ClinicalTrials.gov. Available at: http://www.clinicaltrials.gov/ (Accessed March 28, 2009).

[49] International Standard Randomised Controlled Trial Number (ISRCTN) Register. Available at: http://isrctn.org/ (Accessed March 28, 2009).

[50] University hospital Medical Information Network Clinical Trials Registry (UMIN-CTR). Available at: http://www.umin.ac.jp/ctr/index.htm (Accessed March 28, 2009).

[51] Netherlands Trial Register. Available at: http://www.trialregister.nl/trialreg/index.asp (Accessed March 28, 2009).

In addition to the above registries, the ICMJE accepts registration in any of the primary registries that participate in the WHO International Clinical Trials Registry Platform (ICTRP).[52,53] Authors should check periodically to identify any registries that may be added to this list.

For most clinical studies, the entry of "basic results" data into the registry is required within 12 months of completion of data collection.[54] The ICMJE does not consider results posted in a trial's registry as previous publication if they are presented only as a brief (less than 500 words) structured abstract or table. Journals that are not members of ICMJE are urged to follow the same guideline.[54] When submitting a paper, authors should fully disclose to editors all posting of results of the submitted work or closely related work in registries. When deciding whether to consider a trial report for publication, journal editors may review the study's data fields to ensure that they are complete and informative.

Public Access Requirements of Funding Agencies. United States federal law requires that an electronic version of all peer-reviewed journal manuscripts reporting studies funded wholly or in part by the National Institutes of Health (NIH) must be submitted to the National Library of Medicine's PubMed Central upon acceptance for publication. The material is to be made publicly available no later than 12 months after the official date of publication.[55] The purpose of this policy is to ensure public access to the peer-reviewed, published results of all NIH-funded research; to create an archive of peer-reviewed research publications resulting from NIH funding; and to create a searchable compendium of NIH-funded research to help the agency manage and monitor scientific productivity and set priorities.[56]

The NIH public access instructions[57] and frequently asked questions[58] are available online. There are 4 options for submitting manuscripts to PubMed Central.[59] To ensure compliance, NIH Program Officials will check the citations in grant applications, proposals, or progress reports for PubMed Central Identifiers or appropriate alternatives.[60]

A number of other U.S. and international funding agencies (e.g., the Canadian Institutes of Health Research,[61] Howard Hughes Medical Institute,[62] Wellcome Trust,[63] and the United Kingdom's Medical Research Council[64])

[52] WHO International Clinical Trials Registry Platform (ICTRP). Available at: http://www.who.int/ictrp/about/details/en/index.html (Accessed March 28, 2009).

[53] International Committee of Medical Journal Editors (ICMJE). Clinical trial registration: looking back and moving ahead. *Ann Intern Med*. 2007; 147:275-7. Available at: http://www.icmje.org/clin_trial07.pdf (Accessed March 28, 2009).

[54] International Committee of Medical Journal Editors (ICMJE). Basic results reporting at ClinicalTrials.gov and "prior publication." Available at: http://www.icmje.org/clinicaltrials.htm (Accessed March 28, 2009).

[55] National Institutes of Health. Public access policy. Available at: http://publicaccess.nih.gov/ (Accessed March 28, 2009).

[56] National Institutes of Health. Policy on enhancing public access to archived publications resulting from NIH-funded research. Notice Number: NOT-OD-05-022, February 3, 2005. Available at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html/ (Accessed March 28, 2009).

[57] NIH public access instructions. Available at: http://publicaccess.nih.gov/ (Accessed March 28, 2009).

[58] NIH public access frequently asked questions. Available at: http://publicaccess.nih.gov/FAQ.htm (Accessed March 28, 2009).

[59] NIH public access submission methods. Available at: http://publicaccess.nih.gov/submit_process.htm (Accessed March 28, 2009).

[60] National Institutes of Health Office of Extramural Research. *Extramural Nexus*. October 2008. Available at: http://grants1.nih.gov/grants/nexus.htm (Accessed March 28, 2009).

[61] The public access requirements of the Canadian Institutes of Health Research. Available at: http://www.cihr-irsc.gc.ca/e/32005.html (Accessed March 28, 2009).

[62] The public access requirements of the Howard Hughes Medical Institute. Available at: http://www.hhmi.org/about/research/sc320.pdf (Accessed March 28, 2009).

[63] The public access requirements of the Wellcome Trust. Available at: http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTD002766.htm (Accessed March 28, 2009).

[64] The United Kingdom's Medical Research Council position statement on public access. Available at: http://www.mrc.ac.uk/Ourresearch/Ethicsresearchguidance/Openaccesspublishing/Positionstatement/index.htm (Accessed March 28, 2009).

have public access requirements. It is the author's responsibility to understand and adhere to the requirements of any agency funding the author's research.

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 (IRB) or complied with the Declaration of Helsinki[65] and/or relevant NIH forms.[66] The researchers must have conducted the study according to the approved protocol and acceptable research standards, including having obtained informed consent of study subjects. Although some IRBs may consider certain types of studies, such as case reports, to be exempt from their approval, IRB review may still be necessary to make that determination. Journal editors may request a copy of the IRB determination letter during manuscript submission. Additionally, authors should obtain written informed consent from the subjects of case reports and written permission to use any identifiable images.

Animal Research. All journals should require formal affirmation that any research involving animals was approved by an animal care and use committee and was conducted according to the approved protocol and acceptable research standards for animal experimentation.

Cell Line Authentication. The problem of cell line contamination and misidentification has been recognized since the 1960s.[67] The issue remains unresolved and there is growing concern over the ongoing, widespread use of misidentified cell lines. Although there is general agreement in the scientific community that this is a serious problem, there is less agreement on the possible solutions.

Cell line authentication is the use of appropriate methods to verify that cell lines used in specific research studies are properly identified. It has been proposed that research using unauthenticated cell lines should not be funded or published.[67] The NIH, which has published a policy notice on the issue,[68] finds that solution impractical, relying instead on peer reviewers of grants and manuscripts. Their role, in part, is to examine the experimental methods used by researchers and assure that they are appropriate.

Authors should be aware of the potential problem to ensure that they are presenting valid research. Journal editors and publishers are currently determining how to address the issue of cell line authentication, so guidelines may be developed in the future.

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2.2.7 Resources and Case Studies

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[65] World Medical Association Declaration of Helsinki. Ethical principles for medical research involving human subjects. October 22, 2008. Available at: http://www.wma.net/e/policy/b3.htm (Accessed March 28, 2009).

[66] National Institutes of Health, Office of Human Subjects Research (OHSR). OHSR information sheets/forms. Available at: http://ohsr.od.nih.gov/info/info.html (Accessed March 28, 2009).

[67] Nardone RM. Eradication of cross-contaminated cell lines: A call for action. *Cell Biol Toxicol* 2007;23:367–372.

[68] NIH notice regarding authentication of cultured cell lines. Available at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-017.html (Accessed March 28, 2009).

Council of Science Editors (CSE). CSE recommendations for group-author articles in scientific journals and bibliometric databases. Available at: http://www.councilofscienceeditors.org/publications/group_authorship.pdf (Accessed March 28, 2009).

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National Institutes of Health, Office of Human Subjects Research (OHSR). OHSR information sheets/forms. Available at: http://ohsr.od.nih.gov/info/info.html (Accessed March 28, 2009).

Utiger RD, for the Education Committee of the World Association of Medical Editors. A syllabus for prospective and newly appointed editors. Available at: http://www.wame.org/syllabus.htm#policies/resources/editor-s-syllabus (Accessed March 28, 2009).

World Medical Association Declaration of Helsinki. Ethical principles for medical research involving human subjects. October 22, 2008. Available at: http://www.wma.net/e/policy/b3.htm (Accessed March 28, 2009).

2.3 Reviewer Roles and Responsibilities

Peer review is 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 quality of the peer-review process and the quality of the editorial board are cited as primary influences 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 typically volunteer their time and expertise. In most circumstances, at least 2 reviewers are asked to evaluate a manuscript; some journals request 3 reviews. Some journals also solicit an independent statistical review. In cases of controversy or strong disagreement regarding the merits of the work, an additional review may 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 are needed to obtain a thorough evaluation of a paper.

In addition to fairness in judgment and expertise in the field, peer reviewers have significant responsibilities toward authors, editors, and readers.

Peer reviewer responsibilities toward authors include:

- Providing written, unbiased feedback in a timely manner on the scholarly merits and the scientific value of the work, together with the 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
- Maintaining the confidentiality of the review process: not sharing, discussing with third parties, or disclosing the information in the reviewed paper

Peer reviewer responsibilities toward editors include:

- Notifying the editor immediately if unable to review in a timely manner and providing the names of potential other reviewers
- Complying with the editor's written instructions on the journal's expectations for the scope, content, and quality of the submitted work
- Providing a thoughtful, fair, constructive, and informative critique of the submitted work
- Determining scientific merit, originality, and scope of the work; indicating ways to improve it; and recommending acceptance or rejection using whatever rating scale the editor deems most useful
- Noting any ethical concerns, such as any violation of accepted norms of ethical treatment of animal or human subjects or substantial similarity between the reviewed manuscript and any published paper or any manuscript concurrently submitted to another journal
- Alerting the editor about any potential personal or financial conflict of interest and declining to review when a possibility of a conflict exists (see section 2.3.2)
- Refraining from direct author contact without the editor's permission

Peer reviewer responsibilities toward readers include:

- Ensuring that the published article adheres to the journal's standards
- Protecting readers from incorrect or flawed research and from studies that cannot be validated by others
- Ensuring that the article cites all 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 excluding reviewers from the same institution as that of the author(s) and by asking reviewers to disclose any potential conflict of interest. Reviewers may 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 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 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 clearly enough that editors and authors can understand the basis of the comments. The reviewer should ensure that an observation or argument that has been previously reported be accompanied by a relevant citation and should immediately alert the editor when he or she becomes aware of duplicate publication.

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. Reviewers need not be expert in every aspect of an article's content, but they should accept an assignment only if they have adequate expertise to provide an authoritative assessment. A reviewer without

the requisite expertise is at risk of recommending acceptance of a submission with substantial deficiencies or rejection of a meritorious paper. In such cases, the 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 and/or discuss their concerns with the editor.

Disclosure of conflict of interest. To the extent possible, the review system 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 the role of 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 within 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 merely 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," or "single-blind," system in which 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, or double-blind, system, in which the reviewers do not know the identity of the authors or their affiliation.

There is an ongoing discussion about whether the popular model of partially masked peer review is optimal, and some journals and editors[69] propose a fully open system in which all participants know the others' 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 is 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 of 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 (in which 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.

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2.3.5 Resources and Case Studies

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Black N, van Rooyen S, Godlee F, Smith R, Evans S. What makes a good reviewer and a good review for a general medical journal? *JAMA*. 1998;280:231–233.

Committee on Publication Ethics (COPE). COPE members have access to an archive of case reports, several of which concern the review process. Information available at: http://publicationethics.org/ (Accessed March 28, 2009).

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Evans AT, McNutt RA, Fletcher SW, Fletcher RH. The characteristics of peer reviewers who produce good quality reviews. *J Gen Intern Med*. 1993;8:422–428.

Living Spring Journal. Guidelines for reviewers. Available at: http://www.bath.ac.uk/lispring/journal/reviewgd.htm (Accessed March 28, 2009).

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[69] Rennie D. Freedom and responsibility in medical publication: setting the balance right. *JAMA*. 1998;280:300–302.

Rennie D. Freedom and responsibility in medical publication: setting the balance right. *JAMA*. 1998;280:300–302. Available at: http://www.ama-assn.org/public/peer/7_15_98/pv71038x.htm (Accessed March 28, 2009).

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van Rooyen S, Godlee F, Evans S, Smith R, Black N. Effect of blinding and unmasking on the quality of peer review: a randomized trial. *JAMA*. 1998;280:234–237.

World Association of Medical Editors (WAME). Reviewer conflict of interest. Available at: http://www.wame.org/ethics-resources/reviewer-conflict-of-interest/ (Accessed March 28, 2009).

2.4 Sponsor Roles and Responsibilities

Sponsoring agencies (e.g., pharmaceutical, device, or equipment firms; contract research organizations; or academic entities) are involved primarily in the following aspects of the publication process:

- Authorship/contributorship
- Process control (content and journal selection)
- Disclosure of funding sources and sponsor involvement
- Access to, and provision of, data
- Copyright
- Proper sponsor conduct and ethical practices
- Trial registration and dissemination of findings

Communication between the investigators and the study sponsor, as between the authors and the journal, is crucial to ensuring that the sponsor's role is properly defined and fulfilled. For manuscripts that identify the contributions of a sponsor, the publisher may request the name and contact information of a sponsor representative to serve as a corresponding agent. This representative may be a third party (i.e., not directly employed by the sponsor but acting in an agent capacity).

2.4.1 Authorship/Contributorship

Manuscripts reporting the results of a sponsored study may include one or more of the sponsor's employees or consultants as authors. These authors are bound to the authorship requirements set forth by the publishing journal. For biomedical journals, these requirements are often based on the International Committee of Medical Journal Editors (ICMJE) Uniform Requirements for authorship.[70] In particular, all listed authors must make significant intellectual contributions to the manuscript. It is inappropriate for the sponsoring organization to offer guest or "courtesy" authorship, which is defined as the inclusion on the author byline of an individual who does not meet the criteria for authorship.

Ghost authorship is also inappropriate. The World Association of Medical Editors (WAME)[71] defines ghost authorship as any substantial contribution to the writing of a manuscript by an individual whose role is not disclosed in the manuscript. Unattributed contributions to data analysis may also constitute ghost authorship. If a medical writer contributes to a manuscript, sponsors should consult the authorship guidelines of the publishing journal, the ICMJE,[70] the European Medical Writers Association (EMWA),[72] and the American Medical Writers Association (AMWA)[73] to determine whether the contribution qualifies the medical writer for authorship.

[70] International Committee of Medical Journal Editors (ICMJE). Uniform requirements for manuscripts submitted to biomedical journals. II.A Authorship and contributorship. Available at: http://www.icmje.org/#author (Accessed March 28, 2009).

[71] World Association of Medical Editors (WAME) policy statement on ghost writing initiated by commercial companies. Available at: http://www.wame.org/wamestmt.htm#ghost (Accessed March 28, 2009).

[72] Jacobs A, Wager E. European Medical Writers Association (EMWA) Guidelines on the role of medical writers in developing peer-reviewed publications. *Curr Med Res Opin*. 2005;21:317–321. Available at: http://www.emwa.org/Mum/EMWAguidelines.pdf (Accessed March 28, 2009).

[73] American Medical Writers Association (AMWA). Position statement on the contribution of medical writers to scientific publications. Available at: http://www.amwa.org/default.asp?Mode=DirectoryDisplay&id=308 (Accessed March 28, 2009).

Journal editors typically require corresponding authors to be forthright about all contributors and to comply with the journal's criteria for authorship. If a writer does not meet authorship criteria, he or she may meet the journal's criteria for acknowledgment. In such cases, the journal may ask the publication's authors to obtain a signed statement from all acknowledged contributors detailing their contributions. Journals may also ask for disclosure of conflicts of interest from acknowledged contributors. (See section 2.2 for more information on authorship.)

2.4.2 Process Control (content and journal selection)

Authorial independence from undue sponsor influence is essential. In the course of executing usual authorship forms, editors and publishers may require authors to state that they submit the manuscript of their own free will, without undue influence from the sponsor. Authors may be required to state that they agree with the interpretation of the results and the conclusion as stated in the manuscript. Whatever their relationship with the sponsor, authors must ensure that the results and their interpretation as presented in the submitted manuscript are based solely on scientific criteria (regardless of the outcome). Additionally, the authors should be free to submit the manuscript to the journal they consider most appropriate.

2.4.3 Disclosure of Funding Sources and Sponsor Involvement

Sponsors should be transparent in disclosing financial or 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 study's funding source(s). The sponsor's relationship with the authors should be clearly and fully stated in the conflict of interest disclosure signed by the authors and should mention all support given by the sponsor, including the provision of research materials, employment, honoraria, grants, and all other types of material and financial support. Editors may also ask that the sponsor's specific role in manuscript development be declared (i.e., the role of sponsor in research design, data collection/analysis, decision to publish, choice of journal, etc.). If the sponsor played no such roles in the study, this should also be stated (see the ICMJE authorship requirements[70] 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 study data set and the right to use all study data for 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 provide investigators and journals with clearly outlined policies for sharing data and materials, including providing information to repositories. Sponsors should be prepared to cooperate with authors in fulfilling journal requests for data. Some journals may require registration of phase 3 clinical trials. Although some registries do not specify whose responsibility it is to register a clinical trial, it may be the sponsor's responsibility (See section 2.4.7), the author's responsibility (see section 2.2.6), or both (see also the Council of Science Editors endorsement of the ICMJE's statement on clinical trial registration[74]). Sponsors and investigators should avoid entering into agreements that limit the sharing of data and materials supporting their published claims. Sponsors should be aware that many journals

[74] Council of Science Editors (CSE). Endorsement of principles: The ICMJE's statement on clinical trial registration. Available at: http://www.councilscienceeditors.org/editorial_policies/endorsementofprinciples.cfm (Accessed March 28, 2009).

have policies requiring the sharing of data and materials from an accepted manuscript. Authors should be able to remove their names from a manuscript if they are not given complete access to data.

2.4.5 Copyright

Sponsors who claim ownership to the data being reported, along with the manuscript's authors, will be asked to sign over certain publication rights to the journal through copyright transfer or a licensing agreement. Sponsors should be aware of, and must abide by, the terms of these agreements. Resubmission of substantially similar results to another journal, under the direction or influence of the sponsor, may require permission of the copyright holder. Sponsors must 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 Proper Sponsor Conduct and Ethical Practices

Proper sponsor conduct and ethical practices include, but are not limited to:

- Not unduly influencing authors regarding the selection or interpretation of results and/or the formulation of conclusions
- Allowing the authors to decide where to submit a manuscript
- Not pressuring reviewers to favorably assess manuscripts supporting a sponsor's product or device
- Avoiding unwarranted authorship or failure to disclose authorship
- Providing data or materials to the authors as requested
- Disclosing material, financial, or in-kind support

Sponsor misconduct or engagement in unethical practices may be grounds for a journal correction or retraction if such action is deemed appropriate by the journal's editor after a complete and fair investigation (see section 3.0).

2.4.7 Trial Registration and Dissemination of Findings

Trial sponsors are required under United States law to register trials and to report the findings as defined within Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA).[75] The sponsor, along with the trial investigators and publishing journal, should ensure that the appropriate acknowledgments and disclosures include the publicly accessible registration number for each trial submitted for publication.

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[75] Food and Drug Administration Amendments Act of 2007 (FDAAA). Available at: http://www.fda.gov/oc/initiatives/hr3580.pdf (Accessed March 28, 2009).

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International Committee of Medical Journal Editors (ICMJE). Uniform requirements for manuscripts submitted to biomedical journals. Available at: http://www.icmje.org/ (Accessed March 28, 2009).

Jacobs A, Wager E. European Medical Writers Association (EMWA) Guidelines on the role of medical writers in developing peer-reviewed publications. *Curr Med Res Opin*. 2005;21:317–321. Available at: http://www.emwa.org/Mum/EMWAguidelines.pdf (Accessed March 28, 2009).

World Association of Medical Editors (WAME). Ghost writing initiated by commercial companies. Available at: http://www.wame.org/wamestmt.htm#ghost (Accessed March 28, 2009).

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 (see section 2.1). 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 the 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 noneditorial, 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 section 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 organization, or journal owner in the education and training of new editors.

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2.5.1 Resources and Case Studies

American Medical Association Manual of Style: A Guide for Authors and Editors, 10th ed. New York: Oxford University Press; 2007:246–59.

Callaham ML. Journal policy on ethics in scientific publication. *Ann Emerg Med*. 2003;41:82–89.

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Gastel B. The relationship between journal editors and journal owners. *Science Editor*. 2001;24:43.

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World Association of Medical Editors (WAME). The relationship between journal editors-in-chief and owners. Available at: http://www.wame.org/wamestmt.htm#independence (Accessed March 28, 2009).

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 4 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.
- Online usage that results from journal media coverage can lead to additional citations and an increase in the value perceived by librarians.

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 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 preparing press materials, journals should help the media produce 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 impose an embargo 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 the 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 no embargo date is 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 may be 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 the journal's and publisher's (if applicable) 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 that the reporter agrees to honor the embargo, in order to disseminate clear and accurate information regarding a manuscript. The embargo allows the reporter time to cultivate a well-thought-out story.

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2.6.1 Resources and Case Studies

Committee on Publication Ethics (COPE). Available at: http://publicationethics.org/ (Accessed March 28, 2009).

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3.0 IDENTIFICATION OF RESEARCH MISCONDUCT AND GUIDELINES FOR ACTION

3.1 Description of Research Misconduct

Although no standard definition of research misconduct exists, and 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 Joint 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."[76] 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 in which 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.[77] 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.

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[78] 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

[76] Joint consensus conference on misconduct in biomedical research: 28th and 29th October 1999: Consensus statement. The COPE Report 2000. Available at: http://publicationethics.org/static/2000/2000pdf5.pdf (Accessed March 28, 2009).

[77] 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.

[78] World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA*. 2000;284:3043–3045.

institutional or national recommendations for the care and use of laboratory animals is also a serious 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
- Failure to follow the approved protocol during the conduct of 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 or 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 (ICMJE) addresses this last issue in the Uniform Requirements:[79]

> 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 investigators' fabrication or falsification of data. Fabrication refers to the invention, recording, or reporting of data. 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 of the perpetrator is the untruthful portrayal of the ideas or methods as his or her 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' duplication of their own previously published reports without acknowledgment (this is sometimes called self-plagiarism or duplicate publication).

[79] International Committee of Medical Journal Editors (ICMJE). Uniform requirements for manuscripts submitted to biomedical journals. II.E. Privacy and confidentiality. II.E.1. Patients and study participants. Available at: http://www.icmje.org/#privacy (Accessed March 28, 2009).

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3.1.4 Resources and Case Studies

Joint consensus conference on misconduct in biomedical research: 28th and 29th October 1999: consensus statement. The COPE Report 2000. Available at: http://publicationethics.org/static/2000/2000pdf5.pdf (Accessed March 28, 2009).

International Committee of Medical Journal Editors (ICMJE). Uniform requirements for manuscripts submitted to biomedical journals. Available at: http://www.icmje.org (Accessed March 28, 2009).

3.2 International Models for Responding to Research Misconduct

As 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) used, and the sanctions and corrective actions taken after the conclusion of an investigation.

3.2.1 National Bodies Responding to the Problem

Few countries have developed national means of responding to allegations of scientific misconduct. Formal governmental mechanisms exist or are in development in the United States (US), Denmark, Finland, Norway, Sweden, Australia, Canada, and Germany. Many of the national bodies were created in the early 1990s. The most formal, developed, and experienced systems exist in the United States and Denmark. Other nations, such as the United Kingdom, have addressed the problem largely through private bodies.[80]

The governmental bodies that respond to cases of alleged scientific misconduct have a variety of roles. Under most systems, the research institutions employing the accused scientist are responsible for investigating allegations of research misconduct.[81] This is appropriate because they will have access to the personnel and records necessary to conduct a credible investigation. Further, as the recipients of government funds, they should have responsibility for addressing such allegations. Accordingly, most of the governmental bodies[82] serve review and appellate functions for university and research institution investigations and conduct the primary investigation only 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.

The United States

One of the oldest governmental bodies exists in the US. Before 1989, scientific misconduct cases in the US were investigated by individual granting agencies. In 1989, the Office of Scientific Integrity (OSI), part of the US National Institutes of Health (NIH), 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 has as much experience as the NSF and ORI. The US Veteran's Administration has been taking a more active role during recent years, promulgating its own policies and procedures and handling a number of cases.

[80] 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.

[81] This is true under the Australian, Canadian and US systems.

[82] This is true under the model adopted in the Finland, Sweden, and the United States.

Nordic countries

The Nordic countries have been active in establishing national bodies that respond to the problem. The Danish system, established in 1992, is administered 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 no 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).[83] 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.

Australia and New Zealand

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 it has 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.

Canada

In Canada, the Tri-Council—comprising the Medical Research Council of Canada, the Natural Sciences and Engineering Research Council of Canada, and 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, if no institution is identified, informing

[83] Annual reports (in English) are available at: http://en.fi.dk/councils-commissions/the-danish-committees-on-scientific-dishonesty/publications (Accessed March 28, 2009).

the physician-licensing authorities or similar professional bodies. It is unclear whether 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.

United Kingdom

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).[84] Two other bodies in the United Kingdom (UK) have been advocating institutional reform to address allegations of misconduct: the Committee on Publication Ethics (COPE) and the Association of Medical Research Charities (AMRC).

In the UK, governance rules require that an editor who is a practicing clinician or medical researcher 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 by conditions being placed on his or her work (such as a prohibition on conducting research for a certain period or a requirement that all work be 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.

The GMC has charged several 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.

The COPE is a nonstatutory voluntary organization whose members include the publishers and editors of nearly 300 journals throughout Europe, as well as some in Asia and Australasia, whose editors and publishers have adopted the COPE code of conduct.[85] It meets bimonthly; any member is entitled to attend; and all members are encouraged to submit cases for debate. Its council, which determines policy, comprises 4 editors from premier research journals, 2 publishers, an ethicist, and 2 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 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.

The COPE'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 US or Denmark have not succeeded, but organizations representing

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

[85] Committee on Publication Ethics (COPE). Code of conduct. Available at: http://publicationethics.org/code-conduct (Accessed March 28, 2009).

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 (MRC), Association of British Pharmaceutical Industry, the COPE, and other interested parties.[86] The UK Research Integrity Office (RIO) was established in 2006 and created a hotline for individuals to report misconduct or confirm whether certain actions are misconduct. However, the hotline has no investigative powers; therefore, it has not been universally welcomed by the scientific community.

In December 1997, the MRC, the major source of support for biomedical research in the UK, 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.

Germany and Europe

In 1997, Deutsche Forchungsgemeinschaft (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 noncomplying 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,[87] which consists of a chair, the Secretary General of the DFG, and 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."[88]

The European Science Foundation was established in 1974 and issued a report entitled, "Stewards of Integrity: Institutional Approaches to Promote and Safeguard Good Research Practice in Europe." Among other functions, this body serves as an exchange of information for the various countries developing misconduct regulations and policies. At the end of the report, the contact information for the responsible official of each polled country was included to facilitate the flow of information regarding policies.

China

In February 2007, the Chinese Academy of Science released its Declaration of Scientific Concepts, which establishes ethical guidelines for researchers. This code defines misconduct as falsification, fabrication, or plagiarism of research or abuse of scientific research resources. The Ministry of Science and Technology also established a central scientific ethics committee to investigate allegations and impose sanctions.

[86] 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.

[87] Deutsche Forchungsgemeinschaft (DFG). Committee of Inquiry on Allegations of Scientific Misconduct. Available at: http://www.dfg.de/en/dfg_profile/structure/statutory_bodies/joint_committee/joint_committee_commissions_and_committees/scientific_misconduct/index.html (Accessed March 28, 2009).

[88] Max Planck Society for the Advancement of the Sciences. Rules of procedure in cases of suspected scientific misconduct. Available at: http://www.mpg.de/pdf/procedScientMisconduct.pdf (Accessed March 28, 2009).

India

The Society for Scientific Values, founded in 1986, has been investigating various misconduct cases in India. In 2007, the Society investigated 11 cases.

Croatia

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.

Japan

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 investigated by universities or institutes.

Many countries have not developed a national body to respond to scientific misconduct despite widespread awareness of the problem.[89] Although other organizations exist to address problems relating to misuse of animals or humans in experimentation, radiation-handling violations, and financial misconduct with research funding, the advent of organizations that address other forms of scientific misconduct is relatively recent.

3.2.2 Definition of Research Misconduct

The responsibility of the bodies described above 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, 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 the UK, the Association of the British Pharmaceutical Industry defines "research fraud" as the generation of false data with intent to deceive, and the Royal College of Physicians defines "scientific misconduct" as piracy, plagiarism, and fraud.[90] In contrast, the MRC defines scientific misconduct as:

[89] 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.

[90] These terms are further defined as:

> 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.

> 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 Biomedical Research,[91] 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.

The UK Research Integrity Office (RIO) lists the commonly accepted types of misconduct, and makes it clear that interpretation is open to individual determination in each case. The UK RIO[92] describes misconduct in research as:

> In discussing misconduct in research…the following may serve as useful terms by way of guidance. Interpretation of the terms will involve judgments, which should be guided by previous experience and decisions made on matters of misconduct in research.
>
> - Fabrication;
> - Falsification;
> - Misrepresentation of data and/or interests and/or involvement;
> - Plagiarism; and
> - Failure to follow established procedures or to exercise due care in carrying out responsibilities for:
>   - Avoiding unreasonable risk or harm to humans, animals used in research, and the environment.
>   - The proper handling of privileged or private information on individuals collected during the research.

[91] Joint consensus conference on misconduct in biomedical research: 28th and 29th October 1999: consensus statement. The COPE Report 2000. Available at: http://publicationethics.org/static/2000/2000pdf5.pdf (Accessed March 28, 2009).

[92] The UK Research Integrity Office (UK RIO). Procedure for the investigation of misconduct in research, August 2008. Available at: http://www.ukrio.org/resources/UKRIO%20Procedure%20for%20the%20Investigation%20of%20Misconduct%20in%20Research.pdf (Accessed March 28, 2009).

> For the avoidance of doubt, misconduct in research involves acts of omission as well as commission. In addition, the standards by which allegations of misconduct in research should be judged should be those prevailing in the country in question and at the date that the behaviour under investigation took place.
>
> The basis for reaching a conclusion that an individual is responsible for misconduct in research relies on the judgment that there was an intention to commit the misconduct and/or recklessness in the conduct of any aspect of a research project.

Multiple definitions are found even in the US, 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, a component of the National Science and Technology Council, issued a federal definition of misconduct[93] and encouraged all the agencies, including NSF and ORI, to adopt it.

Effective June 16, 2005, the United States Public Heath Service, which administers its integrity program through the ORI, defined research misconduct as:[94]

> Fabrication, falsification, or plagiarism, in proposing, performing, or reviewing research, or in reporting research results.
>
> (a) Fabrication is making up data or results and recording or reporting them.
>
> (b) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
>
> (c) Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
>
> (d) Research misconduct does not include honest error or differences of opinion.

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 follows the White House Office of Science and Technology Policy. Thus, the current NSF definition is:[95]

> (a) *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.

[93] National Science and Technology Council. Federal policy on research misconduct. Available at: http://www.ostp.gov/cs/federal_policy_on_research_misconduct (Accessed March 30, 2009)

[94] Department of Health and Human Services. Public Health Service policies on research misconduct; final rule. 42 CFR Parts 50 & 93. Available at: http://www.nacua.org/documents/HHS_ResearchMisconduct.pdf (Accessed March 28, 2009).

[95] National Science Foundation definition of research misconduct. Available at: http://www.nsf.gov/oig/resmisreg.pdf (Accessed March 28, 2009).

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

(b) *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 US, 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 took place.

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) intentional 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 US 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.[96]

[96] 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."

3.2.3 The Investigation

As stated earlier, under most systems, the university or research institution has primary responsibility for investigating 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 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. Cases have been appealed through the ORI and NSF processes, although such appeals have been limited to less than 6 total. 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.[97] 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."[98] 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,[99] 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.

[97] Parrish D. Improving the scientific misconduct hearing process. *JAMA*. 1997;277:1315–1319.

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

[99] Zawadzki Z, Abbasi K. Polish plagiarism scandal unearthed. *BMJ*. 1998;316:645. Available at: http://www.bmj.com/cgi/content/extract/316/7132/645/i (Accessed March 28, 2009).

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 DCSD does not publish the names of scientists found to have committed scientific misconduct. Under the UK's MRC process, the scientific community, sponsors, and other "interested parties" are informed of findings of misconduct.

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3.3 Reporting Suspect Manuscripts

There have been a number of cases involving allegations of misconduct and manuscripts, including some investigated 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 was made even before the manuscript had been 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 (COPE)[100] 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 (e.g., 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 whose content or authorship may reflect 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 misconduct has been alleged by 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 coauthor 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, 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 coauthors and believe that pursuing publication without listing their names as authors 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 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 (e.g., the ORI). Or, the editor may choose to notify no one. In fact, an editor of *History News Network*

[100] Committee on Publication Ethics (COPE). Algorithms for editors who suspect publication misconduct. Available at: http://publicationethics.org/flowcharts (Accessed March 28, 2009).

indicated that he got so many allegations of plagiarism that he referred only the most notorious cases for investigation.[101] It appears that most editors have chosen to notify the corresponding author of a problem with a manuscript. This approach has the advantages of identifying a potential problem without initiating the required steps in a misconduct investigation, while 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 may attempt to contact all of the authors in the interest of receiving a prompt response, but this potentially increases the risk of a breach of confidentiality and the risk 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 investigations at their institutions upon 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 places the journal into the role of accuser and involves the journal in the misconduct investigation whether it wants to participate 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 case, several threats of such action have been made by counsel in such cases.

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[101] 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 March 28, 2009).

3.4 Digital Images and Misconduct

The revolution in electronic communication has meant that many journals now have a completely electronic workflow. Manuscripts, including both text and figures, are submitted as electronic files, which are then imported into layout templates by production departments. Electronic workflows provide 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 may tempt 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 saw only a printout of the images and could not examine the image files. Electronic workflows make these files available to journal editors. Simple forensic techniques can now reveal manipulations 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 fraud. For the purposes of this section of the 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 (e.g., 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).[102] Examples of guidelines form other publishers can be found here:

Nature[103]

Proceedings of the National Academy of Sciences[104]

Science[105]

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

[103] *Nature*. Image integrity and standards. Available at: http://www.nature.com/authors/editorial_policies/image.html (Accessed March 28, 2009).

[104] *Proceedings of the National Academy of Sciences (PNAS)*. Figure preparation. Available at: http://www.pnas.org/site/misc/iforc.shtml#ix (Accessed March 28, 2009).

[105] *Science*. Resolution, file format, and modification of figures. Available at: http://www.sciencemag.org/about/authors/prep/prep_revfigs.dtl#format (Accessed March 28, 2009).

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:

- 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 (e.g., 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, acceptance of the manuscript may be revoked.

These comprehensive guidelines were developed in 2002 by The Rockefeller University Press and are now used by many other journals.

3.4.2 Enforcing the Guidelines

Examining image files. A simple "forensic" analysis of the images in a figure file can be accomplished by using the basic "Brightness/Contrast" slide bars in Photoshop to reveal inconsistencies in the pattern of background pixilation 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 by Rossner and Yamada (Figure 6 in their article).[102]

Defining misconduct. The Rockefeller University Press has defined 2 types of digital image–related misconduct: inappropriate manipulation and fraudulent manipulation. Inappropriate manipulation refers to adjustment of the image data that violates the established 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 of images from different microscope fields into a single image that appears to be a single field. Fraudulent manipulation refers to adjustment of 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 clear case of "inappropriate manipulation" is detected, the author should be required to resubmit the figure in question with a more accurate representation of the original data. This approach applies only to adjustments for which there are clear solutions to remedy the problems; 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 there is *any* possibility that the manipulation may be fraudulent, the journal editor should be alerted, and the original data should be obtained from the authors for comparison to the prepared figure. Although the Office of Research Integrity (ORI) guidelines for editors indicate that cases of "suspected" misconduct should be reported either to the ORI or to an author's institution,[106] 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.

[106] 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 (Accessed March 28, 2009).

Obtaining original data. Authors' reputations for impeccable research integrity among their scientific peers are vital for success in their careers. Authors will thus be concerned 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 caused by the transfer of images from one computer application to another (e.g., 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.

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 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. Other journals are encouraged to adopt similar procedures.

A policy for reporting misconduct should be developed by each journal (see 3.1, 3.2, and 3.3.) Misconduct can be reported either to an author's institution or to the ORI.[107] 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.

Many institutions that receive Public Health Service (PHS) funding have an ombudsman for allegations of misconduct in science, whom a journal can contact if it decides to report misconduct to an author's institution. Absent an ombudsman, every institution that receives PHS funding has an individual who has signed the PHS "Letter of Assurance," which indicates that the institution will abide by the PHS code of conduct.

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3.4.4 Additional Resources

Office of Research Integrity (ORI). Forensic tools. Available at: http://ori.dhhs.gov/tools/data_imaging.shtml (Accessed March 29, 2009).

Sample correspondence: Editor to author request for original files (e.g., figure files). Available at: http://www.councilscienceeditors.org/editorial_policies/correspondence/reqforfiles.cfm (Accessed March 29, 2009).

[107] The Office of Research Integrity (ORI). Available at: http://ori.dhhs.gov/ (Accessed March 28, 2009).

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, corrections enable the researcher to identify and use correct information, thereby saving time and resources. Third, corrections enhance a journal's reputation for 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 no single 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; it serves millions of researchers through MEDLINE and develops policies annually in response to issues that surface in the biomedical publishing community. The ICMJE Uniform Requirements,[108] 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 organizations provide the greater scientific research community with a useful framework for addressing issues related to correcting the literature.

The following sections examine current literature correction practices, including definitions, a checklist for editors, and examples of language used for correcting the literature.

3.5.1 Definitions

One of the most confusing aspects associated with literature corrections is the terminology journals use to identify 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, which 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 and incorporated into the NLM system in 2004.[109,110] The expression of concern is a label that an editor may use to draw attention

[108] International Committee of Medical Journal Editors (ICMJE). Uniform requirements for manuscripts submitted to biomedical journals. Available at: http://www.icmje.org/ (Accessed March 28, 2009).

[109] S. Kotzin, Chief, Indexing, MEDLINE; written communication, December 2004.

[110] International Committee of Medical Journal Editors (ICMJE). Uniform requirements for manuscripts submitted to biomedical journals. III.B. Corrections, retractions and "expressions of concern." Available at: http://www.icmje.org/#correct (Accessed March 28, 2009).

to possible problems, but it 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 addressed. Literature corrections are typically handled on a case-by-case basis.

The American Physical Society (APS) published the Supplementary Guidelines on Responsibilities of Coauthors and Collaborators[111] (adopted by the APS Council on November 10, 2002), which discuss authorship responsibilities associated with maintaining integrity in what is published. The guidelines also 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."[111] While not all authors who publish are members of the American Physical Sciences, anyone who publishes in that association's journal is held to these standards.

The Society for Neuroscience has been one of the leading professional organizations to address literature corrections that follow a finding of scientific misconduct. In its 1998 publication, "Responsible Conduct Regarding Scientific Communication"[112] 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 (e.g., erratum, retraction, or apologia).
>
> 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.[113]

3.5.3 Corrections and Retractions Related to Misconduct

3.5.3.1 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 whose publications require 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.

[111] American Physical Society. Supplementary guidelines on responsibilities of coauthors and collaborators. Available at: http://www.aps.org/policy/statements/02_2.cfm#supplementary_guidelines1 (Accessed March 28, 2009).

[112] Society for Neuroscience. Responsible conduct regarding scientific communication. Available at: http://web.sfn.org/index.cfm?pagename=responsibleConduct (Accessed March 28, 2009).

[113] Society for Neuroscience. Dealing with possible scientific misconduct. Available at: http://web.sfn.org/index.cfm?pagename=responsibleConduct_dealingWithPossibleScientificMisconduct (Accessed March 28, 2009).

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 manuscripts submitted to or published 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,[114] the ORI report or the voluntary agreement signed by the respondent, and the Departmental Appeals Board decision, if applicable. This notification is sent upon publication of the *Federal Register* notice announcing the PHS findings and administrative actions.[115]

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 coauthor 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 ICMJE's Uniform Requirements—meaning it should be labeled as such, appear in a prominent section of the journal, be listed in the table of contents, and include in its heading the title and citation of the original journal article.[116]

3.5.3.2 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 it relies on a grantee's institution to handle literature corrections related to findings of scientific misconduct.[117]

3.5.4 Processes

Literature corrections, whether in the form of errata or retractions, can be 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, although many do not have specific guidelines.[118,119]

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[114] The Assistant Secretary for Health makes the final PHS decision on findings of research misconduct and the imposition of administrative actions after reviewing the recommendations made by the ORI. See also http://ori.hhs.gov/misconduct/phs_decision.shtml (Accessed March 28, 2009).

[115] 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.dhhs.gov/documents/newsletters/vol8_no1.pdf (p. 13) (Accessed March 28, 2009).

[116] 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 (Accessed March 28, 2009).

[117] J. Kroll, Head of Administrative Investigation, NSF/OIG; written communication, January 2005.

[118] 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.

[119] Scheetz MD. Promoting integrity through "instructions to authors" a preliminary analysis. Available at: http://69.59.142.46/documents/instructions_authors.pdf (Accessed March 28, 2009).

The NLM and the ICMJE's Uniform Requirements describe those persons from whom literature corrections will be accepted.

Of the 2 primary forms of literature corrections, "retractions" can be more difficult to attain. As indicated by the NLM, retractions are issued for the more serious literature corrections. They are most easily published when the responsible author(s) submits the request to the editor. While retractions do not necessarily reflect scientific misconduct, there are instances in which an author found guilty of scientific misconduct has refused 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 should consider their responsibility to report accurate information to their readership. The ORI has had a case in which coauthors and a responsible university official submitted a retraction when the original author refused.[120] Section 3.5.7 below cites other cases in which coauthors submitted retractions after an author guilty of misconduct refused.

As previously discussed, the NLM and 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, in order 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 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

[120] 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.

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.[121]

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 are available in the online NLM fact sheet.[121]

The processes for errata and retractions as addressed in the ICMJE's Uniform Requirements are:

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

[121] National Library of Medicine. Fact sheet: errata, retractions, partial retractions, corrected and republished articles, duplicate publications, comments (including author replies), updates, patient summaries, and republished (reprinted) articles policy for MEDLINE. Available at: http://www.nlm.nih.gov/pubs/factsheets/errata.html (Accessed March 28, 2009).

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.[122]

3.5.5 Editor's Checklist

Because literature corrections may occur at different points during the publication process, no single specific formula is applicable in all situations. Editors typically address these matters on a case-by-case basis. However, there are some general issues that an editor should consider when addressing a literature correction:

What is the nature of the correction request? On the basis of definitions previously outlined, is a correction, retraction, or expression of concern warranted? The type of correction that is published 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 must make the request when authors disagree about the responsibility for the correction. 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. If there is disagreement, the correction should be written by a responsible institutional official or the editor.

What wording 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 wording 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. If the corrections are the product of a scientific misconduct investigation, this would occur after a finding of scientific misconduct has 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.

In addition to those presented above, an editor may need to consider the following questions, which may not have simple answers:

[122] International Committee of Medical Journal Editors (ICMJE). Uniform requirements for manuscripts submitted to biomedical journals. III.B. Corrections, retractions and "expressions of concern." Available at: http://www.icmje.org/#correct (Accessed March 28, 2009).

Is there a statute of limitations for the publication of errata and/or retractions? As an example, there have recently been cases in which figure panel duplications were identified in papers published more than 5 to 10 years ago. Is it reasonable or appropriate to publish a correction or retraction of work that may have been replicated in subsequent publications in the same or other journals? Should it depend on the extent of errors in the original publication? Should it depend on a finding of fraud or misconduct, or is simple error sufficient to warrant a correction or retraction of a paper that is 5 to 10 years old?

Can the same (or different) authors republish findings of a paper that has been retracted for fraud or a simple error? The implicit assumption is that scientific findings that have been retracted either for fraud or simple experimental error are no longer supported by the available data and, therefore, are not valid. If subsequent experiments by the same or a different laboratory "redemonstrate" the retracted scientific conclusions with appropriately robust data, is it appropriate for an editor to consider such a paper for publication in the same journal that published the original manuscript and retraction? Is it appropriate for the editor of another journal to publish such a paper?

If a third party alerts an editor to multiple figure panel duplications within a given published paper, and the authors of the paper assert that these are honest errors in compiling the figures for publication and do not affect the central conclusions, what is the appropriate course of action for the editor to take?

Is the decision as to whether to publish a correction or a retraction impacted by whether the main results have been replicated in subsequent experiments from the same or a different laboratory?

Does the editor have a responsibility to protect published authors from unsubstantiated or spurious allegations of fraud or misconduct, and what is the editor's responsibility in following up on anonymous complaints of fraud?

What is the appropriate course of action for an editor to take regarding allegations of fraud or misconduct that are not covered by ORI or other government funding agencies or institutions?

3.5.6 Other Avenues for Correction and Clarification

Some journals offer options other than formal corrections and clarifications submitted to a journal by the authors of a published paper. These options allow the airing of important critiques and concerns after publication. Such forums offer researchers the opportunity to challenge the results, interpretations, and/or main conclusions of a published research paper, and are often accompanied by a response from the authors of the original paper. Unlike traditional "letters to the editor," these manuscripts are peer reviewed and are indexed by PubMed and/or other indexing services.

Examples of these types of correspondence include:

- Technical Comments (*Science*): These manuscripts can be up to 1000 words long with 15 references and 2 figures or tables. They may be submitted up to 6 months after publication of the original paper in *Science* and are typically accompanied by a formal response from the original authors. The full text of comments and responses are published online only (abstracts appear in print and online).
- Brief Communications Arising (*Nature*): These manuscripts can be up to 600 words long with 15 references and 1 figure or table. They are published online only.
- Matters Arising (*Cell*): These manuscripts are for major challenges to the main message of a published *Cell* paper. They follow the same format and length as *Cell* research articles and are published both in print and online. In most cases, authors of the original *Cell* paper are given an opportunity to provide a written response that is evaluated first by the editors and then may then be sent with the Matters

Arising manuscript to peer reviewers. Depending on the recommendations of the peer reviewers, the response may or may not be published along with the Matters Arising manuscript.

- Correspondence (*Cell)*: These manuscripts can be up to 500 words and are published in print and online with up to 1 figure that is published online only. They are accompanied by a response from authors of original *Cell* paper.

3.5.7 Examples of Literature Corrections

Just as the policies for publishing literature corrections vary, the actual publication of the corrections varies as well. The following section provides examples of literature corrections (errata and retractions) and information about who submitted them. The literature corrections were selected from publicly available sources, and their presentation reflects the authenticity and style of the respective journals.

Examples of Corrections Submitted by Authors

Errata

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;190:164251), 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<.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<.001)."

Retractions

3. *Arterioscler Thromb Vasc Biol*. 2008 July 17 [Epub ahead of print] DOI: 10.1161/01.ATV.0000339045.74426.52 PMID: 18635819. **Retraction** submitted by all authors.

   Wolfort RM, Manriquez R, Stokes KY, Granger DN. Platelet-Derived RANTES Mediates Hypercholesterolemia-Induced Superoxide Production and Endothelial Dysfunction. Arterioscler Thromb Vasc Biol. 2008 July 17. [Epub ahead of print] PMID: 18635819

   The authors wish to retract the above-referenced article due to concerns related to the authenticity and accuracy of the data presented. Since the original data generated for superoxide production and Nox-2 expression by the first author (RMW) could not be found, we are unable to verify the data presented in Figures 1–4 (superoxide production) and

the Table (Nox-2expression). In addition, some of the myography (acetylcholine-induced vasodilation) data sets presented in this manuscript are identical to data sets produced by the first author for other publications. We deeply regret any scientific misconceptions that have resulted from the publication of this manuscript.

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. *Science* 2007;317 (5839):748. DOI: 10.1126/science.317.5839.748b **Partial retraction.**

   Retraction of an Interpretation

   In the Report "Structure of the 8200-year cold event revealed by a speleothem trace element record" (1), we presented a 7762-μm-long ion probe trace element traverse chosen to include the 8200-year event as detected in a previously published laser ablation oxygen isotope study from the same stalagmite (2). The oxygen isotope anomaly was distinct and dropped 8‰ below baseline values to a low value for the entire Holocene of -12‰ and was reproducible on a reverse track. However, recent reanalysis of the calcite believed to contain the oxygen isotope anomaly suggests that the anomaly was probably an analytical artifact possibly caused by laser ablation-induced fracturing during the original analysis (3). Consequently, without the original $\delta^{18}O$ "marker," the precise location in the stalagmite of calcite deposited during the 8200-year event is uncertain.

The trace element data in this Report, previously believed to correspond precisely with the entire 8200-year event, are now believed to represent the hydrological and bioproductivity response in western Ireland to a cold/dry event of uncertain provenance and intensity. The U-Th-derived dates of the event correspond approximately with the 8200-year event in Greenland ice cores, but without the additional guidance of the $\delta^{18}O$ anomaly, the precise timing in relation to the 8200-year event is now somewhat ambiguous. Unfortunately, it is now unlikely that the approximately 114-year duration ion probe track coincides with the entire 8200-year event (if at all); thus, the ~37-year estimate derived for its duration is probably no longer accurate. However, the trace element data remain robust and are interpreted as reflecting colder and drier conditions in western Ireland, followed by the return to more maritime conditions at the end of the first-order trace element anomaly. Additionally, the novel application of annual trace element cycles to build a high-resolution chronology and reconstruct paleoseasonality remains unchanged.

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1. Baldini JU, McDermott F, Fairchild IJ. *Science* 2003;**296**: 2203–2206.
2. McDermott F, Mattey DP, Hawkesworth C. *Science* 2001;**294**:1328.
3. Fairchild IJ, *et al. Earth Sci. Rev*. 2006;**75**:105.

Examples of corrections submitted by editors

Retractions

7. *Proc Natl Acad Sci U S A*. 2004;101:15271. doi: 10.1073/pnas.0406725101. **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.

8. *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.

9. *Science* 20 January 2006;311(5759):335 DOI: 10.1126/science.1124926 **Retraction.**

Editorial Retraction

The final report from the investigation committee of Seoul National University (SNU) (1) has concluded that the authors of two papers published in *Science* (2,3) have engaged in research misconduct and that the papers contain fabricated data. With regard to Hwang *et al*., 2004 (2), the Investigation Committee reported that the data showing that DNA from human embryonic stem cell line NT-1 is identical to that of the donor are invalid because they are the result of fabrication, as is the evidence that NT-1 is a bona fide stem cell line. Further, the committee found that the claim in Hwang *et al*., 2005 (3) that 11 patient-specific embryonic stem cells line were derived from cloned blastocystsis based on fabricated data. According to the report of the Investigation Committee, the laboratory "does not possess patient-specific stem cell lines or any scientific basis for claiming to have created one." Because the final report of the SNU investigation indicated that a significant amount of the data presented in both papers is fabricated, the editors of *Science* feel that an immediate and unconditional retraction of both papers is needed. We therefore retract these two papers and advise the scientific community that the results reported in them are deemed to be invalid.

As we post this retraction, seven of the 15 authors of Hwang *et al*., 2004 (2) have agreed to retract their paper. All of the authors of Hwang *et al*., 2005 (3) have agreed to retract their paper.

Science regrets the time that the peer reviewers and others spent evaluating these papers as well as the time and resources that the scientific community may have spent trying to replicate these results.

Donald Kennedy
Editor-in-Chief

References

1. Investigation Committee Report, Seoul National University, 10 Jan. 2006. (Members: Chairman Myung-Hee Chung, SNU, Uhtaek Oh, SNU, Hong-Hee Kim, SNU, Un Jong Pak, SNU, Yong Sung Lee, Hanyang University, In Won Lee, SNU, In Kwon Chung, Yonsei University, Jin Ho Chung, SNU)
2. Hwang WS, *et al*., Evidence of a Pluripotent Human Embryonic Stem Cell Line Derived from a Cloned Blastocyst, *Science* 2004;303(5664):1669–1674.
3. Hwang WS *et al*., Patient-Specific Embryonic Stem Cells Derived from Human SCNT Blastocysts, *Science* 2005;308(5729):1777–1783.

10. *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 by 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.

11. *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).

Examples of retractions submitted by others

12. *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) promotor 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*.

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-α 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.

Examples of expressions of concern

14. *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.

15. *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.

Example of a retraction that followed an earlier expression of concern

16. *Science* 2006;314(5799), 592. Editorial Expression of Concern.

In the 17 February 2006 issue, we published the study "*CDX2* gene expression and trophectoderm lineage specification in mouse embryos" by K. Deb *et al.* (1). It has come to our attention, through communication with Robert Hall of the Provost's office at the University of Missouri Columbia and the senior author of the paper, R. Michael Roberts of the University of Missouri Columbia, that there is an ongoing investigation of this study by the University of Missouri. We are therefore informing readers that the results reported therein may not be reliable.

Donald Kennedy
Editor-in-Chief

Reference

1. Deb K, Sivaguru M, Yong HY, Roberts RM. *Science* 2006;**311(5763)**, 992–996.

Science 2007;317(5837):450. **Retraction.**

We wish to retract our Report "*CDX2* gene expression and trophectoderm lineage specification in mouse embryos" (1). Allegations of research misconduct were received by the University of Missouri-Columbia (MU) Provost, and an investigation found that the first author (K.D.) engaged in research misconduct by intentionally falsifying and fabricating digital images in the preparation of Figs. 4I; 4N; 4S; 2G; 3, J to L; S2, V to X; and S6, I to K accompanying the *Science* article. In addition, the original raw image files for the majority of the figures in the paper have not been located (the exceptions being the confocal scanning images in Figs. S1, S3, S4, S5, and S6), raising the possibility that the data they represent may also be suspect. We have decided to withdraw the article in its entirety in view of the fact that the paper was founded at least in part on falsified or fabricated images.

The corresponding author (R.M.R.) takes responsibility for placing excessive trust in his co-worker and for not assuring that a complete set of raw data existed at the time the questions first arose about the paper. We deeply regret any scientific misconceptions that have resulted from the publication of this article.

The first author resigned from MU shortly after the allegations of research misconduct were received and could not be found to sign the retraction.

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1. Deb K, Sivaguru M, Yong HY, Roberts RM. *Science* 2006;**311(5763)**:992–996.

(Authorship: Mary Scheetz took the lead in writing this section of the white paper on behalf of the CSE Editorial Policy Committee. Heather Goodell, Emelie Marcus, and Tara Marathe revised this section for the 2009 Update. Members of the Editorial 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 March 29, 2009.)

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 may 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, editors 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. It is the editor's 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, such as the identities of the peer reviewers, for a case they are working on. 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 the need to retain 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. A journal's counsel can explain to opposing counsel the weakness of their client's position without resort to expensive litigation. 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.

3.6.3 Federal Agencies

For a variety of reasons, it is rare for a federal agency to approach a journal editor 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 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 Editorial Policy Committee. Debra Parrish and Jill Filler revised this section for the 2009 Update. Members of the Editorial 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 March 29, 2009.)

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