CSE's White Paper on Promoting Integrity in Scientific Journal Publications, 2012 Update

Editorial Policy Committee (2011-2012)

www.CouncilScienceEditors.org

CSE's White Paper on Promoting Integrity in Scientific Journal Publications, 2012 Update

Editorial Policy Committee (2011-2012)

www.CounsilScienceEditors.org

Kristi Overgaard (Chair)
American Orthopaedic Society for Sports Medicine

Patricia Baskin
American Academy of Neurology

Elizabeth Blalock
Journal of Investigative Dermatology

Howard Browman
Institute of Marine Research, Storebø, Norway

Bruce Dancik
NRC Research Press, University of Alberta

Wim D'Haeze
Arena Pharmaceuticals, Inc.

Robert L. Edsall
American Academy of Family Physicians

Jill Filler
American Society for Pharmacology and Experimental Therapeutics

Heather Goodell
American Heart Association

Angela Hartley
Association of Women's Health, Obstetric and Neonatal Nurses

Kenneth Kornfield
American Society of Clinical Neurology

Christine Laine
Annals of Internal Medicine

Jennifer Mahar
Wiley-Blackwell

Emilie Marcus
Cell

Stephen Morrissey
New England Journal of Medicine

Debra Parrish
Parrish Law Offices

Michael Roy
American Psychiatric Publishing

Daniel Salsbury
Proceedings of the National Academy of Sciences

Mary Scheetz
Research Integrity Consulting, LLC

Diane Scott-Lichter
American Association for Cancer Research

Gene P. Snyder
Envision Pharma

Anna Trudgett
American Society of Hematology

Editorial Policy Committee (2008-2009)

Heather Goodell (Chair)
American Heart Association

Elizabeth Blalock
Journal of Investigative Dermatology

Bruce Dancik
NRC Research Press, University of Alberta

Robert L. Edsall
American Academy of Family Physicians

Jill Filler
American Society for Pharmacology and Experimental Therapeutics

Angela Hartley
Association of Women's Health, Obstetric and Neonatal Nurses

Michael Kahn
Shire Development Inc.

Christine Laine
Annals of Internal Medicine

Jennifer Mahar
Wiley-Blackwell

Tara Marathe
Science

Harvey Marcovitch, CSE Board Liaison
Chair, Committee on Publication Ethics

Editorial Policy Committee (2005-2006)

Acknowledgments

The CSE Editorial Policy Committee acknowledges the work of the previous committees, which served as a basis for this paper. The Committee is indebted to the CSE Board and reviewers, whose support and timely input made this White Paper possible.

Special thanks to SPi for providing composition services and the PDFs, and to The Sheridan Group for printing this version of the White Paper.

Preferred Citation

Scott-Lichter D and the Editorial Policy Committee, Council of Science Editors. CSE's White Paper on Promoting Integrity in Scientific Journal Publications, 2012 Update. 3rd Revised Edition. Wheat Ridge, CO: 2012.

Council of Science Editors

10200 W 44th Ave Suite 304
Wheat Ridge, CO 80033
Phone: 720-881-6046
Email: CSE@CouncilScienceEditors.org
Web: www.councilscienceeditors.org

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/i4a/pages/index.cfm?pageid=3331

Table of Contents

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 and it was last updated in 2009. For the 2012 Update, we substantially revised and updated each section; included information on citation manipulation, publication planning by study sponsors, and ethical conduct of sponsors; reorganized the section on reporting suspect manuscripts; updated information on international models for responding to research misconduct; and provided more recent 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. Kristi Overgaard revised this section for the 2012 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 30, 2012.)

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. Depending upon the relationship between the editor and publisher for particular journals, some of the roles and responsibilities between the two may overlap in some of the following:

Editor Responsibilities toward Authors

- Providing guidelines to authors for preparing and submitting manuscripts
- Providing a clear statement of the Journal's policies on authorship criteria
- Treating all authors with fairness, courtesy, objectivity, honesty, and transparency
- 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
- Being vigilant in avoiding the possibility of editors and/or referees delaying a manuscript for suspect reasons
- 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 and anyone involved in the peer review process (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, in cooperation with the publisher, 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 employed was 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. Some journals may require and publish a statement of author contribution for each article. 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,[a] 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 were summarized in the manuscript) to the editor when requested or indicate where (site) the data can be found.
- 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)*[b] 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.

[a] A sample disclosure form can be found at: http://jama.ama-assn.org/cgi/data/295/1/103/DC1/1 (Accessed March 9, 2012).

[b] *Proceedings of the National Academy of Sciences (PNAS)* Information for authors. Available at: http://www.pnas.org/misc/iforc.shtml (Accessed March 9, 2012).

- Obtain permission from the copyright owner to use/reproduce copyrighted content (e.g., figures and tables) in the submitted manuscript, if applicable.[c]
- Provide written permission from any potentially identifiable individuals referred to or shown in photographs in the manuscript.
- Copyright transfer statement[d] or licensing agreement.[e]

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).[f, 5]
- Adherence to the CONSORT statement,[6] which helps standardize reports of randomized trials.
- The use of the STARD flow diagram and checklist[7] for reporting diagnostic tests.
- Compliance with MOOSE guidelines[8] for reporting meta-analyses and systematic reviews of observational studies.
- Adherence to STROBE checklists[9] for the reporting cohort, case-control, and cross-sectional observational studies.
- Adherence to QUOROM guidelines[10] for reporting meta-analyses and systematic reviews of randomized controlled trials.
- Adherence to the MIAME standards[11] for reporting microarray experiments.
- Adherence to any discipline-specific standards for data sharing and/or open access archiving.

A resource that provides information about many of the reporting guidelines is the EQUATOR network.[12]

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 referees with the proper expertise is the most common method to ensure manuscript quality. However, editors or associate 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.

Referees are chosen by the editors or by associate editors or members of the editorial board to whom the task has been delegated. 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 or double blind); however, although masked, the identity of the author(s) may be known by the reviewers based on the area of research. Many journals follow the

[c] 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 9, 2012).

[d] A sample copyright transfer agreement is available at: http://circres.ahajournals.org/misc/AHA-CTA08-2008.pdf (Accessed March 9, 2012).

[e] A sample licensing agreement is available at: http://www.nature.com/nbt/pdf/nbt_license.pdf (Accessed March 9, 2012).

[f] Some guidelines for registering clinical trials can be found at: http://jama.ama-assn.org/cgi/content/full/292/11/1363 (Accessed March 9, 2012).

practice of keeping reviewer identities anonymous to the authors (single masked or single blind). 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)
- Ensuring that all involved in the publication process understand that it is inappropriate to manipulate citations by, for example, demanding that authors cite papers in the journal[13, 14]
- 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.[15, 16] Sample correspondence related to this topic is available on the CSE website.[17]
- Providing a mechanism for a further discussion on the scientific merits of a paper, such as by publishing letters to the editor, inviting commentaries, article blogs, 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)
- Working with the publisher to attract the best manuscripts and research that will be of interest to readers
- In some instances, a publisher may put pressure on an editor to publish a review or article in an effort to increase reprint sales. The editor has a responsibility to readers and the scientific community to resist such pressure[18]

Journal Ownership

Journals are typically owned by professional societies or associations, foundations, universities, hospitals, research institutions, libraries, governmental organizations, non-profit 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
- Adhering to the owner's and publisher's fiscal policies towards the Journal, at least in so much as they do not encroach upon editorial independence
- 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 editors have editorial freedom, comprising both authority and autonomy. It should be recognized that this is a difficult challenge and, therefore, editors should not hesitate to consult peers and/or organizations, such as the CSE, should concerns or uncertainties arise.

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 material."[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 before 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, 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 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. Editors who may potentially receive DURC submissions should consider establishing best practices for processing these manuscripts.

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

An editor essentially is responsible for what appears in his or her journal. 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 section 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

Much of the above may be laid out in a contract. The terms of the contract should specify the duration of the editor's appointment and the grounds for termination, from both sides.

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 – consistent with established industry standards – 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 section 2.6).

2.1.3 Conflicts of Interest

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

Editors should set and regularly monitor a conflict of interest policy for editors, reviewers, editorial board members, editorial staff, and authors.[15, 16] Sample correspondence related to this topic is available on the CSE website.[17] 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. This can only be achieved if all parties involved in the peer-review process disclose any and all conflicts and allow the Editor to decide how they should be handled. It is also important to recognize that an Editor and/or reviewer can be impartial while nonetheless being in conflict of interest. Since the perception of conflict of interest is detrimental to a journal's reputation, avoiding even the perception of conflict of interest should be a priority. Enforcement of these policies must also be considered: practices to deal with premeditated or inadvertent breaches 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.

- ***Personal conflicts***. Editors should avoid making decisions on manuscripts that conflict with their own interest, such as those submitted from their department or by research collaborators, co-authors (in the case of collaborators or co-authors, some time period should be established, such as "for the past five years"), competitors, or those addressing an issue in which they stand to gain financially (e.g., stock in a company whose product is discussed in the article). If they may have a perceived or actual conflict of interest, editors should delegate handling of any decision to other editors with decision-making responsibility. Also, editors should submit their own manuscripts to the journal only if full masking of the process can be ensured (e.g., anonymity of the peer reviewers and lack of access to records of their own manuscript). Journals should have a procedure in place to guide the handling of submissions by editors, associate editors, editorial board members, and colleagues/students of any of these to allow for peer review and decision making that avoids any conflict of interest. Editorials and/or opinion pieces are an exception to this rule.
- ***Financial conflicts***. The most evident type of potential conflict of financial interest arises when an individual or organization may benefit financially from a decision to publish or to reject a manuscript. Financial conflicts may include salary, grants from a company with an interest in the results, honoraria, stock or equity interests, and intellectual property rights (patents, royalties, and copyrights). Some examples of potential direct and indirect financial conflicts of interest that should be avoided are given below.

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

  Direct: A reviewer gains key knowledge 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. Similarly, 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.

  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***. Other nonfinancial conflicts of interest should also be avoided or disclosed. Some of these include personal, political, academic, and religious conflicts. Examples are listed below.
  - A reviewer evaluating a manuscript reporting research results similar to 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 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 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*,[g] the American Society of Hematology's journal *Blood*,[h] and the American Academy of Neurology's journal *Neurology*.[i]

- 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 Citation Manipulation

Most metrics of scholarly performance, including the Journal Impact Factor (JIF), are based on citations to published articles. This may generate strong temptation to inappropriately increase citations, something that is referred to as citation manipulation or citation gaming.

Citation manipulation refers to any systematic practice that inappropriately pressures authors to cite material with the primary goal of boosting citation rates. The CSE considers all such practices unacceptable.

The following forms of citation manipulation (for the purpose of increasing citation rates) have been reported:[14, 29-36]

- ***Coercion***. At some point during the peer-review process, editors (or anyone else involved in the process) request that authors add citations from their own journal (or a journal from the same publisher).
- ***Editorials***. Editors write editorials in which a disproportionate number of articles from their own journal are cited.
- Reviewers suggesting citations of their own work. Reviewers may suggest that authors cite their articles.

[g] *Annals of Internal Medicine* conflict of interest information is available at: http://www.annals.org/site/shared/author_conflict.xhtml (Accessed March 9, 2012).

[h] *Blood* copyright transfer and conflict of interest disclosure form. Available at: http://bloodjournal.hematologylibrary.org/site/forms/copyright_transfer.xhtml (Accessed March 9, 2012).

[i] *Neurology* disclosure agreement form. Available at: http://www.neurology.org/misc/DisclosureFormDummyForRef.pdf (Accessed March 9, 2012).

- ***Self-citation***. Authors cite disproportionately large numbers of their own articles in all or most of their publications.
- ***Citation swapping***. A group of colleagues (perhaps students or research associates of a particular researcher) agrees to preferentially and regularly cite each other's articles in all or most of their publications.

It should be stressed that some of the practices described above are only inappropriate if the additional citations requested do not add significantly to the scholarly content of the manuscript (i.e., the intent of the request is dubious). To alleviate such concerns, the CSE recommends that editors deal with such issues by clearly informing authors that they need not feel pressured to cite articles simply because they have been requested to do so, especially if the request does not appear to have scientific merit.

Anybody involved in the peer-review process can become a party to citation manipulation. Therefore, it is every participant's responsibility to judge how reasonable such requests are. Stakeholders in the peer-review and editorial process should be alerted to citation manipulation and bring concerns to the attention of the editor, publisher, or other accountable party. Journals may also decide to publish a policy statement condemning citation manipulation practices. It should be noted that most impact factor formulas monitor when self-citation by a journal reaches an unacceptable level. Although such behavior may result in a short-term gain, the strategy may not work in the long-term.

2.1.6 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.

2.1.7 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.

Some journals publish annual editorial audits,[j] 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.

[j] An example of an editorial audit is available at: http://www.conbio.org/Publications/Newsletter/Archives/2008-8-August/newsl013.cfm (Accessed March 9, 2012).

2.1.8 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 section 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.

2.1.9 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 section 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.[37-42] Sample correspondence related to this topic is available on the CSE website.[17]

2.1.10 Considering Appeals for Reconsideration of Rejected Manuscripts

Despite editors' best efforts to solicit fair and unbiased reviews to evaluate manuscripts fairly, and to make decisions that are in the best interest of the journal and its readers, authors may still want to challenge editorial decisions. Editors should have a policy in place to address complaints and help resolve these issues, although it is not easy to explain to an author that the research reported in his or her manuscript does not warrant publication in comparison 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 potentially acceptable, and the process and procedures that will be followed in handling the resubmitted manuscript.

2.1.11 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.[43] Sample correspondence related to this topic is available on the CSE website.[17] 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 articulates 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.[44-47] Sample correspondence related to this topic is available on the CSE website.[17]

2.1.12 References

1. Federation of American Societies for Experimental Biology (FASEB). Animals in research and education. Available at: http://www.faseb.org/Policy-and-Government-Affairs/Science-Policy-Issues/Animals-in-Research-and-Education.aspx (Accessed March 9, 2012).
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 9, 2012).
3. University of California, San Francisco, additional research links. Available at: http://www.research.ucsf.edu/arc/index.asp (Accessed March 9, 2012).
4. *JAMA* Instructions for authors. Available at: http://jama.ama-assn.org/site/misc/ifora.xhtml (Accessed March 9, 2012).
5. The Council of Science Editors' endorsement statement of the ICMJE policy regarding clinical trial registration is available at: http://www.councilscienceeditors.org/i4a/pages/index.cfm?pageid=3377 (Accessed March 9, 2012).
6. The CONSORT statement. Available at: http://www.consort-statement.org (Accessed March 9, 2012).

7. STARD flow diagram. Available at: http://www.clinchem.org/cgi/content/full/49/1/1 (Accessed March 9, 2012).
8. MOOSE guidelines. Available at: http://jama.ama-assn.org/cgi/content/full/283/15/2008 (Accessed March 9, 2012).
9. STROBE statement. Available at: http://www.strobe-statement.org/ (Accessed March 9, 2012).
10. QUORUM guidelines. Available at: http://www.consort-statement.org/mod_product/uploads/QUOROM%20Statement%201999.pdf (Accessed March 9, 2012).
11. MIAME standards. Available at: http://www.mged.org/Workgroups/MIAME/miame_1.1.html (Accessed March 9, 2012).
12. The EQUATOR network. Available at: http://www.equator-network.org/ (Accessed March 9, 2012).
13. Kleinert S, Wager E. Responsible research publication: international standards for editors. A position statement developed at the 2nd World Conference on Research Integrity, Singapore, July 22-24, 2010. Section 2.3 Journal metrics and decision-making. Available at: http://publicationethics.org/files/International%20standard_editors_for%20website_11_Nov_2011.pdf (Accessed March 9, 2012).
14. Wilhite AW, Fong EA. Coercive citation in academic publishing. *Science.* 2012;335:42-43.
15. Committee on Publication Ethics (COPE). What to do if a reviewer suspects undisclosed conflict of interest (CoI) in a submitted manuscript (flowchart). Available at: http://www.publicationethics.org/resources/flowcharts (Accessed March 9, 2012).
16. Committee on Publication Ethics (COPE). What to do if a reader suspects undisclosed conflict of interest (CoI) in a published article (flowchart). Available at: http://www.publicationethics.org/resources/flowcharts (Accessed March 9, 2012).
17. Council of Science Editors. Sample correspondence. Available at: http://www.councilscienceeditors.org/i4a/pages/index.cfm?pageid=3335 (Accessed March 9, 2012).
18. Marcovitch H. Editors, publishers, impact factors, and reprint income. *PLoS Med*. 2010;7:e1000355. Available at: http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000355 (Accessed March 9, 2012).
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 9, 2012).
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 9, 2012).
21. USA PATRIOT Act. Available at: http://www.fincen.gov/statutes_regs/patriot/ CSE White Paper_Ch-01(Accessed March 9, 2012).
22. Journal Editors and Authors Group. Statement on Scientific Publication and Security. *Science* 2003;299(5610):1149. Available at: www.sciencemag.org/site/feature/data/security/statement.pdf (Accessed March 9, 2012).

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 9, 2012).
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 CD. 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 9, 2012).
26. International Committee of Medical Journal Editors (ICMJE). Uniform requirements for manuscripts submitted to biomedical journals. Available at: http://www.icmje.org (Accessed March 9, 2012).
27. Bates T, Anic A, Marusic M, Marusic A. Authorship criteria and disclosure of contributions. *JAMA*. 2004;292:86-88.
28. International Committee of Medical Journal Editors (ICMJE). Uniform requirements for manuscripts submitted to biomedical journals. Conflicts of interest. Available at: http://www.icmje.org/ethical_4conflicts.html (Accessed March 9, 2012).
29. Arnold DN, Fowler KK. Nefarious numbers. *Notices of the AMS*. 2011;8:434-437.
30. Browman HI, Stergiou KI (Eds). 2008. The use and misuse of bibliometric indices in evaluating scholarly performance. *Ethics in Science and Environmental Politics*. 2008;8:1-107.
31. Brumback RA. Impact factor wars: Episode V-The empire strikes back. *Journal of Child Neurology*. 2009;24:260-262.
32. Epstein D. Impact factor manipulation. *The Write Stuff, The Journal of the European Medical Writers Association*. 2007;16(3):133-134.
33. Falagas ME, Alexiou VG. The top-ten in journal impact factor manipulation. *Archivum Immunologiae et Therapiae Experimentalis*. 2008;56(4):223-226.
34. Metz K. Bureaucrats, researchers, editors, and the impact factor – a vicious circle that is detrimental to science. *Clinics*. 2010;65:937-940.
35. Smeyers P, Burbules NC. How to improve your impact factor: questioning the quantification of academic quality. *Journal of Philosophy of Education*. 2011;45:1-17.
36. The PLoS Medicine Editors. The impact factor game. *PLoS Medicine*. 2006;3(6):e291. http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0030291 (Accessed March 9, 2012).
37. Committee on Publication Ethics (COPE). Changes in authorship – Corresponding author requests addition of extra author before publication (flowchart). Available at: http://www.publicationethics.org/resources/flowcharts (Accessed March 9, 2012).
38. Committee on Publication Ethics (COPE). Changes in authorship – Corresponding author requests removal of author before publication (flowchart). Available at: http://www.publicationethics.org/resources/flowcharts (Accessed March 9, 2012).
39. Committee on Publication Ethics (COPE). Changes in authorship – Request for addition of extra author after publication (flowchart). Available at: http://www.publicationethics.org/resources/flowcharts (Accessed March 9, 2012).

40. Committee on Publication Ethics (COPE). Changes in authorship – Request for removal of author after publication (flowchart). Available at: http://www.publicationethics.org/resources/flowcharts (Accessed March 9, 2012).
41. Committee on Publication Ethics (COPE). What to do if you suspect redundant (duplicate) publication – Suspected redundant publication in a submitted manuscript (flowchart). Available at: http://www.publicationethics.org/resources/flowcharts (Accessed March 9, 2012).
42. Committee on Publication Ethics (COPE). What to do if you suspect redundant (duplicate) publication – Suspected redundant publication in a published article (flowchart). Available at: http://www.publicationethics.org/resources/flowcharts (Accessed March 9, 2012).
43. Committee on Publication Ethics (COPE). What to do if you suspect an ethical problem with a submitted manuscript (flowchart). Available at: http://www.publicationethics.org/resources/flowcharts (Accessed March 9, 2012).
44. Committee on Publication Ethics (COPE). What to do if you suspect plagiarism – Suspected plagiarism in a submitted manuscript (flowchart). Available at: http://www.publicationethics.org/resources/flowcharts (Accessed March 9, 2012).
45. Committee on Publication Ethics (COPE). What to do if you suspect plagiarism – Suspected plagiarism in a published article (flowchart). Available at: http://www.publicationethics.org/resources/flowcharts (Accessed March 9, 2012).
46. Committee on Publication Ethics (COPE). What to do if you suspect fabricated data – Suspected fabricated data in a submitted manuscript (flowchart). Available at: http://www.publicationethics.org/resources/flowcharts (Accessed March 9, 2012).
47. Committee on Publication Ethics (COPE). What to do if you suspect fabricated data – Suspected fabricated data in a published article (flowchart). Available at: http://www.publicationethics.org/resources/flowcharts (Accessed March 9, 2012).

2.1.13 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 9, 2012).

American Society for Pharmacology and Experimental Therapeutics. Authorship responsibility, financial disclosure, and copyright transfer. Available at: http://jpet.aspetjournals.org/misc/JPET_copyright_form.pdf (Accessed March 9, 2012).

Annals of Internal Medicine. Authorship Issues. Available at: http://www.annals.org/site/misc/ifora.xhtml#criteria-and-policy (Accessed March 9, 2012).

Biophysical Journal. Copyright permission form. Available at: http://www.mednet.cl/medios/servicios/mednet/copyright_permission_form.pdf (Accessed March 9, 2012).

Bossuyt PM, Reitsma JB, Bruns DE, et al; for the STARD Group. Towards complete and accurate reporting of studies of diagnostic accuracy: the STARD Initiative. *Clin Chem*. 2003; 49:1-18.

Brazma A, Hingamp P, Quackenbush J, et al. Minimum information about a microarray experiment (MIAME): toward standards for microarray data. *Nature Genetics*. 2001;29:365-371.

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.

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 9, 2012).

Neurology. Authorship, non-financial, and financial disclosure form. Available at: http://www.neurology.org/misc/DisclosureFormDummyForRef.pdf (Accessed March 9, 2012).

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 9, 2012).

Stroup DF, Berlin JA, Morton SC, et al. Meta-analysis of observational studies in epidemiology: a proposal for reporting. *JAMA*. 2000;283:2008-2012.

(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. Howard Browman and Bruce Dancik revised this section for the 2012 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 30, 2012.)

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 Authorship Responsibilities

Trust is fundamental to scientific communication: trust that the authors have accurately reported their methods and findings, trust that authors have disclosed all potential conflicts of interest, and trust that editors have exercised sufficient diligence to ensure accurate reporting and disclosure by authors. Unfortunately, problems with authorship are not uncommon and can threaten the integrity of scientific research.[1] With the aim to decrease such problems, this section focuses on principles to guide authorship-related decisions, policies, practices, and responsibilities.

2.2.1 Authorship

Authors are generally defined as persons who have contributed sufficiently to a scientific report to be listed on the byline of the published report. Many journals provide guidelines on authorship in their instructions for authors. Some professional and research funding organizations and academic institutions also provide such guidance. Principles, customs, and practices regarding authorship differ from one scientific discipline to another. This document aims to summarize common principles to guide authorship across scientific disciplines.

Principles related to authorship with general consensus include the following:

- Identification of authors and other contributors is the responsibility of the people who did the work (the researchers) not the people who publish the work (editors, publishers). Researchers should determine which individuals have contributed sufficiently to the work to warrant identification as an author.
- Individuals who contributed to the work but whose contributions were not of sufficient magnitude to warrant authorship should be identified by name in an acknowledgments section.
- All individuals who qualify for authorship or acknowledgment should be identified. Conversely, every person identified as an author or acknowledged contributor should qualify for these roles.
- Individuals listed as authors should review and approve the manuscript before publication.
- Editors should require authors and those acknowledged to identify their contributions to the work and make this information available to readers.
- The ultimate reason for identification of authors and other contributors is to establish accountability for the reported work.

There is less agreement about the best way to ask about and report contributions, whether being an author implies accountability for only parts of the work they specifically did or for the entire paper, and whether editors should set firm criteria to distinguish authors from acknowledged contributors.

Within biomedicine, many journals have adopted the definition of the International Committee of Medical Journal Editors (ICMJE), which defines authorship by the following criteria: 1) substantial contributions to conception and design, 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.[2] While a person who has made these three contributions clearly warrants byline authorship, there is growing concern about the relevance of this definition as the complexity of scientific research and its communication increases. It is difficult to prescribe a defined set of contributions that meet the minimal conditions for authorship.[3-7]

Further, the contributions necessary to complete a body of scientific work differ from discipline to discipline and even among different types of studies within a single discipline. The NIH defines authorship a bit more flexibly than the ICMJE. According to the NIH, "For each individual the privilege of authorship should be based on a significant contribution to the conceptualization, design, execution, and/or interpretation of the research study, as well as on the drafting or substantively reviewing or revising the research article, and a willingness to assure responsibility for the study." [8]

The Committee on Publication Ethics (COPE), whose membership includes more than 4000 journals from all research fields, acknowledges that "there is no universally agreed definition of authorship, although attempts have been made ... As a minimum, authors should take responsibility for a particular section of the study."[9]

The Council of Science Editors, aware of the differences in the requirement for authorship in different fields, began to consider updating authorship and contributorship recommendations during a special Retreat on Authorship at the 2009 CSE Annual Meeting. Journal editors, researchers, and representatives of the academic community from different disciplines presented their experiences and views on authorship and journal authorship policies. The conclusions of the retreat are reflected in the common principles listed above as well as in the statements that follow.

Authors are individuals identified by the research group to have made substantial contributions to the reported work and agree to be accountable for these contributions. In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which of their co-authors are responsible for specific other parts of the work. In addition, an author should have confidence in the integrity of the contributions of their co-authors. All authors should review and approve the final manuscript.

There is consensus about some types of contributions that do not alone justify identification as an author. Professional writers who participated only in drafting of the manuscript and did not have a role in the design or conduct of the study or the interpretation of results should be identified in the acknowledgements section along with information about potential conflicts of interest including whether they were compensated for the writing assistance and, if so, by which entity(ies). It is unacceptable to neglect to identify such individuals. Other contributions that alone do not justify authorship include: assisting the research by providing advice, providing research space, departmental oversight, obtaining financial support, isolated analyses, or providing reagents/patients/animals/other study materials.

2.2.2 Contributorship Models

In the 1990s as a response to the difficulties with defining authorship in science, some scientific publishing stakeholders began to advocate for a "contributorship model" in which published articles include a contributor list rather than an author byline and an acknowledgments section. Advocates of this model propose that doing so would better enable editors to elicit actual contributions from authors and to convey a more accurate sense of each author's responsibility for the study.[10, 11]

This model of "contributorship" has been adopted by a number of major biomedical journals. 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.[10-11] Under this model, authors are also expected to designate their functional role within the group (e.g., principal investigator, coinvestigator, statistician, contributing author).[10-11] It is argued that this additional layer of disclosure contributes to greater transparency on the part of authors.[12]

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,[12] and to gain from authors what Jerome Kassirer has described as "public responsibility for [article] content."[13] 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.[12, 14, 15]

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.[16] 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.[17, 18]

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.

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[19] 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:[17]

- 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.[17]

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. An example of this would be technical laboratory or writing assistance; the specific contribution should be noted. 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. Those acknowledged should disclose potential conflicts of interest.

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.[17] Some journals specify how many authors they will accept in the author byline. Sample correspondence related to this topic is available on the CSE website.[20]

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 Sample correspondence related to this topic is available on the CSE website.[20]

2.2.6 Author Responsibilities

Confidentiality. The author-editor relationship is founded on confidentiality. Authors should hold all communication between themselves and the journal in confidence. Authors should designate a specific contact for all communication about the manuscript throughout peer review and (if accepted) the publication process. Authors should observe journal policy on communication with external peer reviewers (the policy may vary depending on whether a journal uses masked or nonmasked peer review) and should observe journal policy on prepublication embargoes (see 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. Sample correspondence related to this topic is available on the CSE website.[20]

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. Authors should expect editors to publish all relevant disclosures with their accepted manuscript. Sample correspondence related to this topic is available on the CSE website.[20]

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.[k]

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.[l]

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 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.

[k] Examples of disclosure forms are available at: http://www.nejm.org/userimages/ContentEditor/1277392443758/ICMJEDisclosureForm0521101RE.pdf (Accessed Accessed March 9, 2012) and http://mts-npp.nature.com/letters/NPPcoi.pdf (Accessed March 9, 2012).

[l] Examples of a contributorship forms available at: http://www.springer.com/cda/content/document/cda_downloaddocument/ABJSCTAwSigLines.pdf?SGWID=0-0-45-495798-p173705903 (Accessed March 9, 2012).

Data Sharing. Data sharing is the practice of making data used for scholarly research available to other investigators.[21] Authors should be aware of their data sharing responsibilities imposed by their funding agencies. The goal of this policy is to promote reproducibility and availability of underlying data sets. At the beginning of a study the authors should consider where they will submit their data and should consider the journals they may want to submit their study and review the data sharing policies for each journal.

Registration of Clinical Trials. ICMJE's member journals[22] 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.[23, 24] 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.[24] 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[25]
- ClinicalTrials.gov[26]
- International Standard Randomised Controlled Trial Number (ISRCTN) Register[27]
- University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR)[28]
- Netherlands Trial Register[29]

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).[30, 31] Authors should check periodically to identify any registries that may be added to this list. Sample correspondence related to this topic is available on the CSE website.[20]

For most clinical studies, the entry of "basic results" data into the registry is required within 12 months of completion of data collection.[32] 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.[32] 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.[33] 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.[34]

The NIH public access instructions[35] and frequently asked questions[36] are available online. There are 4 options for submitting manuscripts to PubMed Central.[37] To ensure compliance, NIH Program Officials will check the citations in grant applications, proposals, or progress reports for PubMed Central Identifiers or appropriate alternatives.[38]

A number of other U.S. and international funding agencies (e.g., the Canadian Institutes of Health Research,[39] Howard Hughes Medical Institute,[40] Wellcome Trust,[41] and the United Kingdom's Medical Research Council[42]) 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 subject's research on which a submission is based was approved by an institutional review board (IRB) or complied with the Declaration of Helsinki[43] and/or relevant NIH forms.[44] The researchers must have conducted the study according to the approved protocol and acceptable research standards, including having obtained informed consent of study subjects. Sample correspondence related to this topic is available on the CSE website.[20] 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. Sample correspondence related to this topic is available on the CSE website.[20]

Cell Line Authentication. The problem of cell line contamination and misidentification has been recognized since the 1960s.[45] 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.[45] The NIH, which has published a policy notice on the issue,[46] 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.

2.2.7 References

1. Marušić A, Bošnjak L, Jerončić A. A systematic review of research on the meaning, ethics and practices of authorship across scholarly disciplines. *PLoS One*. 2011;6(9):e23477. Epub 2011 Sep 8. Available at: http://www.plosone.org/article/info%3Adoi%2F10.1371%2Fjournal.pone.0023477 (Accessed March 9, 2012).
2. International Committee of Medical Journal Editors (ICMJE). Authorship and Contributorship. http://www.icmje.org/ethical_1author.html (Accessed March 9, 2012).
3. Cottingham K. The Ethics of Authorship: Feature Overview—How Should Authorship be Decided? *Science*. March 30, 2001. Available at: http://sciencecareers.sciencemag.org/career_magazine/previous_issues/articles/2001_03_30/noDOI.1470170286102423077 (Accessed March 9, 2012).

4. Noble M. the Ethics of Authorship: Policies for Authorship of Articles Submitted to Scientific Journals. *Science*. March 30 2001. Available at: http://sciencecareers.sciencemag.org/career_magazine/previous_issues/articles/2001_03_30/noDOI.9203462371499238483 (Accessed March 9, 2012).
5. Wilcox L. The Ethics of Authorhip: An Ombudsperson's Perspective. *Science*. March 30, 2001. Available at: http://sciencecareers.sciencemag.org/career_magazine/previous_issues/articles/2001_03_30/noDOI.14314302689040751822 (Accessed March 9, 2012).
6. The Ethics of Authorship: Does it Take a Village to Write a Paper? *Science*. March 30, 2001. Available at: http://sciencecareers.sciencemag.org/career_magazine/previous_issues/articles/2001_03_30/noDOI.2580479737297545632 (Accessed March 9, 2012).
7. Gottesman M. The Ethics of Authorship: Authorship by prior Agreement—Principles and Pitfalls. *Science*. March 30, 2001. Available at: http://sciencecareers.sciencemag.org/career_magazine/previous_issues/articles/2001_03_30/noDOI.17090511604525562351 (Accessed March 9, 2012).
8. National Institutes of Health. Guidelines for the conduct of Research in the Intramural Research program at NIH. Available at: http://sourcebook.od.nih.gov/ethic-conduct/Conduct%20Research%206-11-07.pdf (Accessed March 9, 2012).
9. Albert T, Wager E. How to handle authorship disputes: a guide for new researchers. The COPE Report 2003. Available at: http://publicationethics.org/files/u2/2003pdf12.pdf (Accessed March 9, 2012).
10. Rennie D, Yank V, Emmanuel L. When authorship fails: a proposal to make contributors accountable. *JAMA.* 1997;278:579-585.
11. Yank V, Rennie D. Disclosure of researcher contributions: a study of original research articles in The Lancet. *Ann Intern Med.* 1999;130:661-670.
12. 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.
13. Kassirer JP. Authorship criteria. *Science*. 1995;268:785-786.
14. Committee on Publication Ethics (CPE). What to do if you suspect ghost, guest or gift authorship (flowchart). Available at: http://publicationethics.org/resources/flowcharts (Accessed January 11, 2012).
15. Committee on Publication Ethics (COPE). How to spot authorship problems (flowchart). Available at: http://publicationethics.org/resources/flowcharts (Accessed March 9, 2012).
16. Flanagin A, Rennie D. Acknowledging ghosts. *JAMA*. 1995;273(1):73.
17. American Medical Association Manual of Style: A Guide for Authors and Editors, 10th edition. Oxford: Oxford University Press; 2007:128-140.
18. Laine C, Mulrow CD. Exocising ghosts and unwelcome guests. *Ann Intern Med.* 2005; 143:611-612.
19. Council of Science Editors (CSE). The CSE recommendations for group-author articles in scientific journals and bibliometric databases. Available at: http://www.councilscienceeditors.org/i4a/pages/index.cfm?pageid=3373 (Accessed March 9, 2012).
20. Council of Science Editors. Sample correspondence. Available at: http://www.councilscienceeditors.org/i4a/pages/index.cfm?pageid=3335 (Accessed March 9, 2012).
21. Data Sharing Definition http://en.wikipedia.org/wiki/Data_sharing (Accessed March 9, 2012).

22. 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/journals.html (Accessed March 9, 2012).
23. 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.nejm.org/doi/full/10.1056/NEJMe058127 (Accessed March 9, 2012).
24. International Committee of Medical Journal Editors (ICMJE). Obligation to register clinical trials. Available at: http://www.icmje.org/publishing_10register.html (Accessed March 9, 2012).
25. Australian New Zealand Clinical Trial Registry. Available at: http://www.anzctr.org.au/Survey/UserQuestion.aspx (Accessed March 9, 2012).
26. ClinicalTrials.gov. Available at: http://www.clinicaltrials.gov/ (Accessed March 9, 2012).
27. International Standard Randomised Controlled Trial Number (ISRCTN) Register. Available at: http://isrctn.org/ (Accessed March 9, 2012).
28. University Hospital Medical Information Network Clinical Trials Registry (UMIN-CTR). Available at: http://www.umin.ac.jp/ctr/index.htm (Accessed March 9, 2012).
29. Netherlands Trial Register. Available at: http://www.trialregister.nl/trialreg/index.asp (Accessed March 9, 2012).
30. WHO International Clinical Trials Registry Platform (ICTRP). Available at: http://www.who.int/ictrp/about/details/en/index.html (Accessed March 9, 2012).
31. 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.nejm.org/doi/full/10.1056/NEJMe078110 (Accessed March 9, 2012).
32. International Committee of Medical Journal Editors (ICMJE). Basic results reporting at ClinicalTrials.gov and "prior publication." Available at: http://www.icmje.org/update_fdaaa.html (Accessed March 9, 2012).
33. National Institutes of Health. Public access policy. Available at: http://publicaccess.nih.gov/ (Accessed March 9, 2012).
34. 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 9, 2012).
35. NIH public access instructions. Available at: http://publicaccess.nih.gov/ (Accessed March 9, 2012).
36. NIH public access frequently asked questions. Available at: http://publicaccess.nih.gov/FAQ.htm (Accessed March 9, 2012).
37. NIH public access submission methods. Available at: http://publicaccess.nih.gov/submit_process.htm (Accessed March 9, 2012).
38. National Institutes of Health Office of Extramural Research. *Extramural Nexus*. October 2008. Available at: http://grants1.nih.gov/grants/nexus.htm (Accessed March 9, 2012).
39. The public access requirements of the Canadian Institutes of Health Research. Available at: http://www.cihr-irsc.gc.ca/e/32005.html (Accessed March 9, 2012).
40. The public access requirements of the Howard Hughes Medical Institute. Available at: http://www.hhmi.org/about/research/sc320.pdf (Accessed March 9, 2012).

41. 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 9, 2012).
42. 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 9, 2012).
43. World Medical Association Declaration of Helsinki. Ethical principles for medical research involving human subjects. October 22, 2008. Available at: http://www.wma.net/en/30publications/10policies/b3/index.html (Accessed March 9, 2012).
44. 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 9, 2012).
45. Nardone RM. Eradication of cross-contaminated cell lines: A call for action. *Cell Biol Toxicol.* 2007;23:367-372.
46. 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 9, 2012).

2.2.8 Resources and Case Studies

Committee on Publication Ethics (COPE). Guidelines. Available at: http://publicationethics.org/resources/guidelines (Accessed March 9, 2012).

International Committee of Medical Journal Editors (ICMJE). Uniform requirements for manuscripts submitted to biomedical journals. Available at: http://www.icmje.org (Accessed March 9, 2012).

National Cancer Institute, National Institutes of Health. Informed consent template for cancer treatment trials (English language). May 23, 2006. Available at: http://www.cancer.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs/page3 (Accessed March 9, 2012).

Utiger RD, for the Education Committee of the World Association of Medical Editors (WAME). A syllabus for prospective and newly appointed editors. Available at: http://www.wame.org/syllabus.htm#policies/resources/editor-s-syllabus (Accessed March 9, 2012).

(Authorship: Michael Vasko took the lead in writing this section of the white paper on behalf of the CSE Editorial Policy Committee. Kristi Overgaard and Sharon Naron revised this section for the 2009 update. Christine Laine and Jennifer Mahar revised this section for the 2012 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 30, 2012.)

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 solicited to evaluate a manuscript; some journals request 3 reviews. This may be required in situations where review by a statistician is needed. In cases of controversy or strong disagreement regarding the merits of the work, an additional review may also be solicited or one of the journal's editors might give an evaluation. 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

- 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 the journal's readers
- Avoiding personal comments or criticism
- Maintaining the confidentiality of the review process: not sharing, discussing with third parties, or disclosing information from the reviewed paper

Peer-reviewer responsibilities toward editors[1-4]

- Notifying the editor immediately if unable to review in a timely manner and providing the names of potential other reviewers
- 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)
- Complying with the editor's written instructions on the journal's expectations for the scope, content, and quality of the review
- Providing a thoughtful, fair, constructive, and informative critique of the submitted work, which may include supplementary material provided to the journal by the author
- 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 which may be known to the reviewer
- Refraining from direct author contact

Sample correspondence related to this topic is available on the CSE website.[5]

Peer-reviewer responsibilities toward readers

- Ensuring that the methods are adequately detailed to allow the reader to judge the scientific merit of the study design and be able to replicate the study, if desired
- 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. Some journals encourage authors to suggest preferred reviewers and reviewers they would prefer to be excluded.

Ideally, 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 believe there is a potential conflict of interest, 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 the forms in an online submission system, the e-mail sent to request the review, 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.[6-7] Sample correspondence related to this topic is available on the CSE website.[5] 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 anonymous comments should be courteous and capable of withstanding public scrutiny. Some journals ask reviewers to provide two sets of comments: one for the author and the other for the editor only. The latter can sometimes be more candid and can recommend that the manuscript be accepted or rejected (something that arguably should not be part of comments to the author).

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[7]
- 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 single 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[8] 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.

2.3.5 Rewarding Reviewers

Some journals find it useful to publicly thank reviewers for their generous volunteer efforts. This may take the form of a published list of reviewers that appears in the journal on a regular (annually, semiannually) basis. Journals may also offer continuing medical education credits for completed reviews.

2.3.6 References

1. Committee on Publication Ethics (COPE). What to do if a reviewer suspects undisclosed conflict of interest (CoI) in a submitted manuscript (flowchart). Available at: http://publicationethics.org/files/u2/05A_CoI_Submitted.pdf (Accessed March 9, 2012).
2. Committee on Publication Ethics (COPE). What to do if you suspect redundant (duplicate) publication – Suspected redundant publication in a submitted manuscript (flowchart). Available at: http://publicationethics.org/files/u2/01A_Redundant_Submitted.pdf (Accessed March 9, 2012).
3. Committee on Publication Ethics (COPE). What to do if you suspect plagiarism – Suspected plagiarism in a submitted manuscript (flowchart). Available at: http://publicationethics.org/files/u2/02A_Plagiarism_Submitted.pdf (Accessed March 9, 2012).
4. Committee on Publication Ethics (COPE). What to do if you suspect fabricated data – Suspected fabricated data in a submitted manuscript (flowchart). Available at: http://publicationethics.org/files/u7140/Flowchart%20Fabricated%20A%20revised%20May%202011.pdf (Accessed March 9, 2012).
5. Council of Science Editors. Sample correspondence. Available at: http://www.councilscienceeditors.org/i4a/pages/index.cfm?pageid=3335 (Accessed March 9, 2012).
6. Committee on Publication Ethics (COPE). What to do if you suspect an ethical problem with a submitted manuscript (flowchart). Available at: http://publicationethics.org/files/u2/06_Ethics_Submitted.pdf (Accessed March 9, 2012).
7. Committee on Publication Ethics (COPE). What to do if you suspect a reviewer has appropriated an author's ideas or data (flowchart). Available at: http://publicationethics.org/files/u2/07_Reviewer_misconduct.pdf (Accessed March 9, 2012).

8. 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 9, 2012).

2.3.7 Resources and Case Studies

American Society of Plant Biologists (ASPB). ASPB ethics in publishing: ASPB policies and procedures for handling allegations of editorial misconduct. Available at: http://www.aspb.org/publications/editorialethics.cfm (Accessed March 9, 2012).

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). Available at: http://publicationethics.org/ (Accessed March 9, 2012).

American Chemical Society. Ethical guidelines to publication of chemical research, January 2000. Available at: http://pubs.acs.org/userimages/ContentEditor/1218054468605/ethics.pdf (Accessed March 9, 2012).

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.

House of Commons Science and Technology Committee. Peer Review in Scientific Publications. Eighth Reports of Session 2010-12. Available at: http://www.publications.parliament.uk/pa/cm201012/cmselect/cmsctech/856/85602.htm (Accessed March 9, 2012)

International Congress on Peer Review and Biomedical Publication. Available at: http://www.ama-assn.org/public/peer/peerhome.htm (Accessed March 9, 2012).

Living Spring Journal. Guidelines for reviewers. Available at: http://www.bath.ac.uk/lispring/journal/reviewgd.htm (Accessed March 9, 2012).

Lock S. A Difficult Balance: Editorial Peer Review in Medicine. New York, NY: Lippincott Williams & Wilkins; 1985.

Office of Research Integrity, Office of Public Health and Science, US Department of Health and Human Services. Managing allegations of scientific misconduct: a guidance document for editors. Available at: http://ori.dhhs.gov/documents/masm_2000.pdf (Accessed March 9, 2012).

Research Ethics Program, University of California, San Diego. Responsible conduct of research (RCR) internet instruction. Available at: http://ethics.ucsd.edu/courses/integrity/about.html (Accessed March 9, 2012).

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 9, 2012).

(Authorship: Anna Trudgett took the lead in writing this section of the white paper on behalf of the CSE Editorial Policy Committee. Anna Trudgett and Robert Edsall revised this section for the 2009 Update. Stephen Morrissey and Kristi Overgaard revised this section for the 2012 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 30, 2012.)

2.4 Sponsor Roles and Responsibilities

2.4.1 Introduction

Communication among investigators, study sponsor, and medical education and communications companies, as between authors and journal, is crucial to ensure that the sponsor's role is properly defined and exercised. For manuscripts that identify the contributions of a sponsor, the editor and/or publisher may request the name and contact information of a sponsor representative to serve as a corresponding agent, for example to resolve an issue that is best addressed by a person who is not necessarily one of the authors. This representative may be a third party (i.e., not directly employed by the sponsor, but acting in an agent capacity).

Sponsoring organizations, referred to herein as "sponsor," (including but not limited to pharmaceutical, medical device, or biotechnology companies; contract research or manufacturing organizations; or academic or research entities) are involved primarily in the following aspects of the publication process:

- Publication planning
- Authorship
- Process control (content and journal selection)
- Disclosure of conflicts of interest
- Access to and provision of data
- Copyright
- Clinical trial registration and dissemination of findings

Authors, sponsors, and medical education and communications companies share responsibility to publish medical information in the form of a peer-reviewed manuscript or presentation during a scientific conference in a responsible and ethical manner per recommendations included in the Good Publication Practices (GPP2) guidelines.[1]

2.4.1.1 Publication Planning

Publication planning is the process typically used by pharmaceutical, device, and biotechnology companies to coordinate the effective and timely publication of clinical study results. Ideally, a publication plan is designed and managed to support authors "in their efforts to ensure appropriate, efficient, and complete communication."[1] A sound publication plan sets milestones during manuscript preparation in accordance with clinical study progression (e.g., manuscript/abstract submission deadline), identifies topics for new publications (e.g., pooled data analyses, new subgroup analyses), and aids in avoiding duplicate and/or incomplete publications.[1]

Publication planning should be used as a tool to facilitate publication of scientific/clinical data following available guidelines. Publication plans should not be used to favorably influence putative markets for not-yet approved products. When publication planning involves substantial contributions of planners, writers, statisticians, and reviewers to the content of a publication, their respective roles should be disclosed in detail.

2.4.1.2 Authorship

Author designations on manuscripts and other scientific presentations that report results of a sponsored study 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.[2] In particular, each author listed on a publication should fulfill *all* of the following three requirements: "1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; and 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published."[1,2]

Manuscript authors should follow the ICMJE requirements for authorship and apply them consistently for the preparation of sponsored as well as unsponsored publications. Misinterpretations and misuse[3] of these ICMJE requirements should be avoided. It is therefore inappropriate to offer guest or "courtesy" authorship, defined as the inclusion on the author byline of an individual who does not meet the criteria for authorship.

If an individual makes any substantial contribution to the writing of a manuscript and this role is not disclosed in the manuscript, this constitutes "ghost authorship" per the World Association of Medical Editors (WAME).[4] Cases of ghost authorship by the pharmaceutical industry have been reported,[5] as well as by academic institutions;[6] ghost-authored publications have been published by high-impact factor journals.[7] Ghost authorship is ethically unacceptable[1] and may put patients' health at risk.[8] Note that, for example, unattributed contributions to data analyses 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,[2] the European Medical Writers Association (EMWA),[9] and the American Medical Writers Association (AMWA)[10] to determine whether the contribution qualifies the medical writer for authorship.

Journal editors typically require corresponding authors to be forthright about all contributors and to comply with the journal's criteria for authorship. A writer may not meet authorship criteria, yet 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. (Refer to Section 2.2 for more information on authorship.) Substantial contributions (e.g., collecting data, analyzing data, performing statistical analyses, drafting the manuscript, conducting critical review) of all authors listed as well of other contributors who do not meet the author requirements should be listed and disclosed in the publication.[1]

2.4.1.3 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 conclusions as stated in the manuscript. Whatever their relationship with the sponsor, authors must ensure that the results and their interpretation of the results 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 suitable.

2.4.1.4 Disclosure of Conflicts of Interest

The ICMJE guidelines state that "all participants in the peer-review and publication process must disclose all relationships that could be viewed as potential conflicts of interest."[2] Conflicts of interest include financial relationships (e.g., sponsored clinical studies) and nonfinancial relationships (e.g., authors with personal relationships) that can possibly affect professional judgment of the manuscript in question.[1] Disclosure of potential conflicts of interest by all involved with publications, including abstracts and poster presentations for scientific conferences, is critical to enable a reader to assess a publication.

Sponsors should be transparent in disclosing financial or in-kind support provided to authors. Similarly, authors 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 list all support received from 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). If the sponsor played no such roles in the study, this should also be stated (refer to the ICMJE authorship requirements[2] for more details and to the GPP2 guidelines[1] for additional recommendations).

A recent study investigating the impact of industry-sponsored clinical trials on the impact factor and financial income of six major medical journals showed that publication of results of industry-sponsored clinical trials is correlated with increased impact factors and that income generated by reprint sales constitutes a substantial part of some top-tier medical journals' total income.[11] In this respect and to fulfill the ICMJE guidelines in regards of conflicts of interest disclosures, it is highly recommended that journals also disclose financial (e.g., projected increased income due to sales of a reprint of a sponsored publication) and nonfinancial (e.g., editorial staff with a personal relationship within the company that sponsored a given manuscript) relationships in a similar manner as authors are required to do.[5, 11, 12]

2.4.1.5 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, have access to the full data set before author activities begin, and be given enough time to analyze and review the full data set as needed.[1] Editors and publishers may require sponsors to warrant that all authors of the submitted manuscript have full access to all 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. 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 (refer to Section 2.4.1.7), the author's responsibility (refer to Section 2.2.6), or both (refer also to the Council of Science Editors endorsement of the ICMJE's statement on clinical trial registration[13]). 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 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.

2.4.1.6 Copyright

Sponsors who claim ownership to the data being reported, along with the manuscript's authors, may 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.

New manuscripts should not be submitted for consideration to multiple journals at the same time. 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 (e.g., translation into a different language, extensive reanalysis of the already published data).[1, 2]

2.4.1.7 Clinical Trial Registration and Dissemination of Findings

Clinical trial sponsors are required under United States law to register clinical trials and to report the findings as defined within Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA).14 The sponsor, along with the clinical trial investigators and publishing journal, should ensure that the appropriate acknowledgments and disclosures include the publicly accessible registration number for each clinical trial submitted for publication. Sample correspondence related to this topic is available on the CSE website.[15]

2.4.2 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
- Using publications (manuscripts, abstracts, posters) to communicate scientific data and observations, and balanced scientific interpretation and discussion thereof
- Not engaging in or supporting guest and ghost authorship
- Disclosing all financial and nonfinancial relationships that may possibly influence professional judgment of a manuscript or other scientific presentation
- Allowing the authors to decide where to submit a manuscript
- Not pressuring reviewers to favorably assess manuscripts supporting a sponsor's product or device
- Providing all data or materials to the authors and investigators in a timely manner as requested or disclose if the sponsor decides not to make all data available to the authors and investigators
- Registering clinical trials as demanded by law

2.4.3 Concluding Remarks

Sponsor misconduct or engagement in unethical practices may be grounds for a journal correction or retraction if such actions are deemed appropriate by the journal's editor after a complete and fair investigation (refer to Section 3.0). It is important to adhere to the detailed available guidelines[1, 2, 4, 6, 10] that describe ethical practices related to the publication of sponsored research (i.e., research sponsored by the industrial sponsors and research sponsored by biomedical research centers). Engaging in unacceptable and unethical publication practices has resulted, in some cases, in severe penalties and put patients' health at risk.[8]

It is therefore recommended to translate guidelines for the ethical publication of sponsored research into uniform policies, compliance of which should be controlled. Control of policy compliance could be governed by legal offices within the industry and academic research centers, and by journal editors. It is also important that authors, sponsors, peer reviewers, and editors engage frequently in informative discussions about a manuscript submitted for publication to ensure that ethical publication standards are met. Providing applicable ethical guidelines and associated information to individuals involved in the preparation of sponsored research-based publications by the industry as well as by medical research centers might also be beneficial. And most importantly, scientific publications should remain to be a medium to communicate scientific data and observations to the scientific community and the public.

2.4.4 References

1. Graf C, Battisti WP, Bridges D, Bruce-Winkler V, Conaty JM, Ellison JM, Field EA, Gurr JA, Marx ME, Patel M, Sanes-Miller C, Yarker YE, for the International Society for Medical Publication Professionals. Good publication practice for communicating company sponsored medical research: the GPP2 guidelines. *BMJ* 2009;339:b4330.
2. 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/ethical_1author.html (Accessed March 9, 2012).
3. Matheson A. How industry uses the ICMJE guidelines to manipulate authorship¾and how they should be revised. *PLoS Med.* 2011;8:e1001072. Available at: http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1001072 (Accessed March 9, 2012).
4. 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 9, 2012).
5. Egilman DS, Druar NM. Corporate versus public interests: community responsibility to defend scientific integrity. *Int. J. Occup. Environ. Health* 2011;17:181-185.
6. Lacasse JR, Leo J. Ghostwriting at elite academic medical centers in the United States. *PLoS Med*. 2010;7:e1000230. Available at: http://www.plosmedicine.org/article/info:doi%2F10.1371%2Fjournal.pmed.1000230 (Accessed March 9, 2012).
7. Wislar JS, Flanagin A, Fontanarosa PB, DeAngelis CD. Honorary and ghost authorship in high impact biomedical journals: a cross sectional survey. *BMJ* 2011;343:d6128.
8. Fugh-Berman AJ. The haunting of medical journals: how ghostwriting sold "HRT." *PLoS Med*. 2010;7:e1000335. Available at: http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.1000335 (Accessed March 9, 2012).
9. 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 9, 2012).
10. 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 9, 2012).
11. Lundh A, Barbateskovic M, Hróbjartsson A, Gotzsche PC. Conflicts of interest at medical journals: the influence of industry-supported randomised trials on journal impact factors and revenue – cohort study. *PLoS Med*. 2010;7:e1000354. Available at: http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000354 (Accessed March 9, 2012).
12. Marcovitch H. Editors, publishers, impact factors, and reprint income. *PLoS Med*. 2010;7:e1000355. Available at: http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000355 (Accessed March 9, 2012).

13. Council of Science Editors (CSE). Endorsement of principles: The ICMJE's statement on clinical trial registration. Available at: http://www.councilscienceeditors.org/i4a/pages/index.cfm?pageid=3377 (Accessed March 9, 2012).
14. Food and Drug Administration Amendments Act of 2007 (FDAAA). Available at: http://www.fda.gov/oc/initiatives/hr3580.pdf (Accessed March 9, 2012).
15. Council of Science Editors. Sample correspondence. Available at: http://www.councilscienceeditors.org/i4a/pages/index.cfm?pageid=3335 (Accessed March 9, 2012).

(Authorship: Michael Kahn and Heather Goodell took the lead in writing this section of the white paper on behalf of the CSE Editorial Policy Committee. Michael Kahn, Heather Goodell, and Gene Snyder revised this section for the 2009 Update. Wim D'Haeze and Michael Kahn revised this section for the 2012 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 30, 2012.)

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 scientific 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. Editors should have independent authority to select their editorial boards. 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 or owner. 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. An independent and objective 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 scientifically related activities (whether editorial or noneditorial) 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 about submissions 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.

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.

Committee on Publication Ethics (COPE). Code of conduct and best practice guidelines for journal editors. Available at: http://publicationethics.org/files/Code%20of%20conduct%20for%20journal%20editors_0.pdf (Accessed March 9, 2012).

Committee on Publication Ethics (COPE). Code of conduct for journal publishers. Available at: http://publicationethics.org/files/Code%20of%20conduct%20for%20publishers%20FINAL_1.pdf (Accessed January 12, 2012).

Davis RM, Mullner M. Editorial independence at medical journals owned by professional associations. *Sci Eng Ethics*. 2002;8:513-528.

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

Geological Society of America. Ethical guidelines for publication. Available at: http://www.geosociety.org/pubs/ethics.htm (Accessed March 9, 2012).

International Committee of Medical Journal Editors (ICMJE). Uniform requirements for manuscripts submitted to biomedical journals. II.B. Editorship. Available at: http://www.icmje.org/ethical_2editor.html (Accessed March 9, 2012).

World Association of Medical Editors (WAME). Relation of the journal to the sponsoring society. Available at: http://www.wame.org/resources/publication-ethics-policies-for-medical-journals#sponsoring (Accessed March 9, 2012).

World Association of Medical Editors (WAME). The relationship between journal editors-in-chief and owners. Available at: http://www.wame.org/resources/policies#independence (Accessed March 9, 2012).

(Authorship: Stephen Morrissey took the lead in writing this section of the white paper on behalf of the CSE Editorial Policy Committee. Stephen Morrissey and Elizabeth Blalock revised this section for the 2009 Update. Howard Browman and Stephen Morrissey revised this section for the 2012 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 March 30, 2012.)

2.6 Responsibilities to the Media

Journals work with media outlets to ensure that notable scientific advances are accurately 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 the public will understand new scientific findings.
- Media coverage helps authors of scientific articles 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.
- Readership that results from journal media coverage can lead to additional web traffic and citations, increasing the value of the journal to 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 articles scheduled for publication in the journal. Identify newsworthy articles, perhaps in conjunction with a media relations department, sponsoring society, or publisher, and develop plans to highlight these articles in press materials. If an article is considered too specialized to interest the general public, some publishers – society publishers, for example -- provide targeted materials to professionals, such as emails to society members.
- 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. To help journalists assess the importance of the article, press materials should also provide background information, describe study limitations, and include information about authors' potential conflicts of interest, if any.
- In addition to preparing press materials, journals should help the media produce accurate reports by answering questions, supplying advance copies of the article on request, providing contact information for the author or authors who will speak about the article, 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 coverage.

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. 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. 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, when available, should be provided to the media. 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). If a journalist violates the terms of an embargo, the violation should be brought to the attention of his or her news organization. Members of the media who do not honor the embargo may be denied access to future embargoed material.

Journals should inform authors of the intent to prepare press materials for their article and of arrangements that have been made with the media. Study sponsors and funders as well as reporters are expected to follow the media guidelines of the journal. If an author's organization is planning an independent press release or other media strategy,

the timing of the activity 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. Some publishers provide authors with a summary of the impact of their article (media impressions). Such service can be attractive to some authors.

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 an article. The embargo allows the reporter time to cultivate a well-thought-out story.

2.6.1 Resources and Case Studies

Committee on Publication Ethics (COPE). Available at: http://publicationethics.org/ (Accessed March 9, 2012).

Improving public understanding: guidelines for communicating emerging science on nutrition, food safety, and health. *J Natl Cancer Inst*. 1998;90:194-199. Available at: http://jncicancerspectrum.oxfordjournals.org/cgi/content/full/jnci;90/3/194 (Accessed March 9, 2012).

Fontanarosa FB, DeAngelis CD. *The Importance of the Journal Embargo. JAMA.* 2002;288(6):748-750. Available at http://jama.ama-assn.org/content/288/6/748.full (Accessed March 9, 2012).

Loscalzo J, Bonow RO, Jacobs AK. Coronary Calcium Screening and the American Heart Association News Embargo. *Circulation.* 2004; 110: 3504-3505. Available at http://circ.ahajournals.org/content/110/23/3504.full (Accessed March 9, 2012).

Godle F. Breaking the Embargo. *BMJ 2008; 337.* Available at www.bmj.com/content/337/bmj.a2852.full (Accessed March 9, 2012).

(Authorship: John Ward and Jennifer Mahar took the lead in writing this section of the white paper on behalf of the CSE Policy Committee. Jennifer Mahar revised this section for the 2009 Update. Stephen Morrissey and Heather Goodell revised this section for the 2012 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 30, 2012).

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, likely to arise as scientific methods progress, research misconduct generally falls into one of the following areas:

- Mistreatment of research subjects
- Falsification and Fabrication of data
- Piracy and 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."[1] This section attempts to objectively define research practices that do not meet these subjective standards.

The U.S. Office of Research Integrity defines research misconduct as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results."[2]

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.[3] The ORI definition has a similar statement.[2] 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 or just specimens are being studied. When research involves human subjects or their specimens, failure to adhere to the principles in the Declaration of Helsinki[4] and to seek approval from and adhere to the ethical standards of the appropriate institutional or national committee on human experimentation is a serious form of scientific misconduct. For researchers who study animals, failure to follow institutional or national recommendations for the care and use of laboratory animals is also a 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

Sample correspondence related to this topic is available on the CSE website.[5]

The International Committee of Medical Journal Editors (ICMJE) addresses this last issue in the Uniform Requirements:[6]

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 two 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. Sample correspondence is available on the CSE website.[5]

3.1.3 Piracy and Plagiarism

Piracy is defined as the unauthorized reproduction or use 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.[2]

Plagiarism is a form of piracy that involves the unauthorized use or close imitation of the language (figures images or tables) and thoughts of others and the representation of them as one's own original work without permission or acknowledgment by the author 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).[2] Sample correspondence is available on the CSE website.[5]

3.1.4 References

1. 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 9, 2012).
2. Office of Research Integrity. Definition of Research Misconduct. Available at: http://ori.hhs.gov/misconduct/definition_misconduct.shtml (Accessed March 9, 2012).

3. 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.
4. World Medical Association Declaration of Helsinki: ethical principles for medical research involving human subjects. *JAMA*. 2000;284:3043-3045.
5. Council of Science Editors. Sample correspondence. Available at: http://www.councilscienceeditors.org/i4a/pages/index.cfm?pageid=3335 (Accessed March 9, 2012).
6. 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/ethical_5privacy.html (Accessed March 9, 2012).

(Authorship: Christine Laine took the lead in writing this section of the white paper on behalf of the CSE Editorial Policy Committee. Christine Laine revised this section for the 2009 Update. Gene Snyder and Heather Goodell revised this section for the 2012 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 Directors on March 30, 2012.)

3.2 International Models for Responding to Research Misconduct

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

3.2.1 National Bodies Responding to the Problem

Fairly few countries have developed national responses to allegations of scientific misconduct. Formal governmental mechanisms exist or are in development in Australia, Canada, China, Denmark, Finland, Germany, India, Norway, Poland, Sweden, and the United States. The most formal, developed, and experienced systems exist in the United States and Denmark. Other countries, such as Great Britain, have addressed the problem through largely private bodies.[a] In Europe, the European Science Foundation has offered "The European Code of Conduct for Research Integrity" Presented at the World Conference on Research Integrity in 2010, the European Code of Conduct is a publication which could be considered "a canon for self-regulation."[1] Some of the topics addressed by the Code include International guidelines for good practice rules, recommended principles for investigating research misconduct cases, and text suggested by the OECD Global Science Forum Coordinating Committee for international agreements in conducting international misconduct investigations.

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

Many of the national bodies were created in the early 1990s. One of the oldest governmental bodies exists in the United States. In the United States before 1989, scientific misconduct cases were investigated by individual granting agencies. In 1989, the Office of Scientific Integrity (OSI), part of the United States National Institutes of Health, and the Office of Scientific Integrity Review (OSIR), part of the Office of the Assistant Secretary for Health, were created to address Public Health Service scientific misconduct cases. The offices were staffed with scientists and attorneys were consulted periodically. In 1992, OSI and OSIR merged to create the Office of Research Integrity (ORI). The ORI professional staff is composed of scientists and lawyers. The National Science

[a] 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.

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

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

Foundation (NSF) is the other US federal body that has been most active in the area of scientific misconduct since 1988. It too has blended law and science when evaluating such cases. Other US federal agencies have addressed cases of misconduct, but none have as much experience as the NSF and ORI.

The Nordic countries have been active in establishing national bodies that respond to the problem. The Danish system, established in 1992, is administered by the Danish Committee on Scientific Dishonesty (DCSD), an 8-member committee composed of a High Court Judge and 7 senior medical researchers. During 2002-2003, the committee upheld 2 of 14 cases reported, although in neither case did they find intent or gross negligence. The criteria against which scientific dishonesty are judged are "the existence of falsification or distortion of a scientific message or gross misrepresentation about a person's involvement in the research".[d, 2]

Misconduct activity is also being investigated by institutions in the Netherlands. Specifically, Tilburg University suspended a researcher amid fears that he fabricated data in publications.[3, 4] The Rector Magnificus of the university formed a committee to investigate the effected publications.[4] Shortly thereafter, the University of Groningen started an investigation of the respondent's work while he was affiliated with that institution, and the University of Amsterdam began an investigation into his Ph.D. thesis.[5] According to the University of Tilburg's preliminary report, misconduct is involved in at least 30 papers, with as many as 150 possible publications affected.[6] Following the release of the report, *Science* issued an expression of concern over one of the respondent's publications in early November 2011, only to issue a retraction in December of 2011 with the respondent's apologies.[7]

Another researcher was fired from Erasmus MC in November 2011 after an investigative committee found him guilty of academic misconduct under its policies.[8] According to the report, the researcher did not obtain informed consent from study participants, he inappropriately collected data, and fabricated data.[9] The study itself dealt with the health of patients undergoing surgery and analyzing what factors can reduce the risk of surgery complications; the misconduct did not cause any medical complications for any of the participants.[10] The committee also made several recommendations for avoiding problems such as this in the future, including encouraging the use of data collection checking systems and encouraging department heads to institute measures to prevent researchers from working in isolation without reports or discussions with colleagues.[e]

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. In 2011, Norway published a report detailing an investigation into alleged research misconduct related to a published article.[11] The allegations were raised by Aqua Gen AS in January 2009, sending a letter to the Commission requesting that it evaluate the conclusions that the authors arrived at in the article.[f] The University of Bergen investigated the alleged misconduct, employed anonymous experts, and forwarded to the Commission its report in November 2009 clearing the researchers of any misconduct, finding that there may have been grounds for some criticism.[f] Interestingly, the company which raised the allegations was given an opportunity to comment on the institutional report, because the Commission has a responsibility to make sure the case is "well-informed."[g] Because the Commission was troubled by the anonymity of the experts in the institutional investigation, it decided to investigate the case in May 2010,

[d] Danish Executive Order No. 933, 15 December 1998, section 3, subsection 1.
[e] Reference 10, pp 9-10.
[f] Reference 11, p 5.
[g] Reference 11, p 6.

and sought international experts.[h] It found three respondents not guilty of scientific misconduct, stating that "the points deserving of criticism, neither individually nor taken together, can be regarded as serious according to the criteria of the Code of Scientific Ethics."[i]

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. According to the 2009 Annual Report of the National Advisory Board of Research Ethics in Finland, the total number of organizations, including research institutions and universities, which had signed the guidelines established by the Board in 2002 entitled Good Scientific Practice and Procedures for Handling Misconduct and in Science was 92.[12]

Finally, in 1997, the Swedish Medical Research Council established a special 10-member working group chaired by a judge from the Supreme Administrative Court and including a representative from each of the medical faculties in the country (5 individuals), a representative from the Swedish National Agency for Social Affairs, a representative from the National Medical Product Agency, and 2 laypersons who serve on county council hospital boards.

In 1990, the Australian National Health and Medical Research Council passed a set of guidelines and procedures to be implemented by all institutions applying for grants. Australia recently established a body to address misconduct. The Australian Research Integrity Committee became operational in February 2011, with four appointed members sitting on the Committee.[13] Established by the National Health and Medical Research Council and the Australian Research Council, the Committee supplies a review organization of institutional policies and responses to allegations of research misconduct. The Framework of the Committee states explicitly that the Committee is not to investigate any allegations of research misconduct itself.[14] Moreover, the Committee may not judge the merits of any institutional finding, unless the process used by the institution was flawed and the error affected the finding.[j]

In New Zealand, there is no formal central organization dealing with research misconduct. If misconduct is suspected, it is usual practice to report the matter to the researcher's institution or to an appropriate government agency, such as the Health Research Council, if they have funded the research. Aggrieved doctors can also report their concerns to the New Zealand Medical Council or to the Health and Disability Commission if the ethics of research relates to patients. One problem is that the country is sufficiently small that, as one editor put it, "one hint of a problem and everyone knows."

In Canada, the Tri-Council, comprising the Medical Research Council of Canada, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada, each of which is a Crown corporation independent of the government, has encouraged universities and 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.

[h] Reference 11, p 7.
[i] Reference 11, p 21.
[j] Reference 14, p 6.

Canada recently issued an evidence-based assessment for the federal government intended to support the government in its work in developing research misconduct public policy.[k, 15] The report indicated that Canada needs to develop a positive culture for research integrity promotion and sanctioning. As part of the assessment, the report details models used by other countries to combat research misconduct issues. In August 2011, a consultation was launched within the university sector in an effort to strengthen the current Framework for the Tri-Council's institutional policy review.[16] Currently, universities have the responsibility of investigating research misconduct.

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

In Britain, because no inspectorate exists and because industry has had most of the cases thus far, activity on this problem has been based on referrals by the Association of the British Pharmaceutical Industry to the General Medical Council (GMC).[17] Two other bodies in the United Kingdom have been advocating institutional reform to address allegations of misconduct: the Committee for Publication Ethics (COPE) and the Association of Medical Research Charities (AMRC).

COPE is a non-statutory voluntary organization whose members include editors of 175 journals from throughout Europe, as well as some in Asia and Australasia, whose editors and publishers have adopted the COPE code of conduct.[18] It meets bimonthly, with any member entitled to attend and all members encouraged to submit cases for debate. Its executive committee determines policy and comprises 4 editors from premier research journals as well as a publisher, an official of the GMC, and a biostatistician, and there are plans to include a patient representative.

At its bimonthly 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 where 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 using delay tactics. When editors believes 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.

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

[k] Information also provided by Cate Meechan of the Council of Canadian Academies (Director, Communications).

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

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

In December 1997, the Medical Research Council, 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 Medical Research Council.

In 1997, in Germany, 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 of funding from non-complying institutions. The DFG also appointed 3 ombudsmen to receive complaints. The DFG currently has a standing committee called the Committee of Inquiry on Allegations of Scientific Misconduct and established a chair with 4 additional scientists. Further, the Max Planck Society for the Advancement of the Sciences, the premier research organization in Germany, developed guidelines and procedures for detecting, assessing, and sanctioning research fraud in November 1997 (amended in November 2000), titled, "Rules of Procedure in Cases of Suspected Scientific Misconduct."

Prior to 2011, Polish cases of research misconduct were handled largely by research institutions or universities.[19] The concerns among the scientific community and the Polish government regarding scientific integrity inspired the creation of a national oversight system; misconduct cases that had continued for long periods of time were silently dropped over the years.[19] The new commission will be composed of up to nine members, and its tasks will include creating a national code of conduct for scientists, taking appeals of research misconduct decisions made at other institutions, investigating cases which were not properly investigated at the institutional level, and advocating research integrity.[19]

Recently, Indian scientists began calling for a national office of research integrity that could investigate and impose sanctions upon scientists who commit research misconduct.[20] At a July 2011 meeting organized by Institute of Mathematical Sciences and the Forum for Global Knowledge Sharing, a professor of materials engineering at the Indian Institute of Science illustrated the rising rate of retraction among Indian authors by pointing out that the average retraction rate for Indian authors was 70 per 100,000 papers between 2001 and 2010; 45 of those retractions occurred because of misconduct.[20] By comparison, the retraction rate for Chinese authors was 48 per 100,000 papers published.

There has also been significant activity in China. In late 2009, two researchers were fired from Jinggangshan University after editors from the journal *Acta Crystallographica Section E* retracted 70 published crystal structures that they assert were fabricated.[21] The editors used software that detects errors and chemical features that seem unusual.[21] Many of the crystal structures that were identified did not make sense chemically; the editors claimed that they would be checking all submissions from Jinggangshan University.[21] Concerned about cases such as this, the Chinese science ministry had over 6,000 researchers surveyed with regard to misconduct, and as of January 2010, the results were not reported.[21] However, according to *Nature's* sources, approximately one-third of the surveyed researchers admitted to fabrication, falsification or plagiarism.[21] According to a March 2011 interview with *Nature*, the new president of the Chinese Academy of Sciences Bai Chunli asserted that the CAS graduate school is considering instituting a mandatory class on research ethics to foster a "culture of accountability" from a young age among researchers.[22]

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 most of them are not aware of the research and regulation in the field of research misconduct.

A recent report by the Centre for Evaluation in Education and Science (CEON) for the Serbian science ministry found that approximately 11% of articles published in Serbian journals by Serbian authors were plagiarized.[23] It was also reported that 0.35% of the articles in the Serbian citation index were published in the identical form twice; the director of COEN attributes this particular problem to editors who track manuscripts "manually" forgetting to mark a paper published.[23] Despite the rate of plagiarism, according to the blogger Tatalovic, only six retractions appear from an index search of "retractions" in both English and Serbian from the 445 journals listed there.[23] None of the retractions came from the authors, but rather from the editors.[23] Importantly, the science ministry plans to update its guidelines for evaluating scientific writings by including a piece on plagiarism.[23]

In 2003, the Council of Japan issued a comprehensive report on research misconduct in Japan and recommended that allegations of research misconduct be investigated by third-party committees run by national ministries or scientific societies rather than universities or institutes. A researcher at Dokkyo University School of Medicine recently had a second article retracted from a journal due to duplicate image publication.[24] According to a blog post, journals have retracted his work eight times for the reuse of images.[24]

Unfortunately, there are many countries that have not developed a national body to respond to the problem of scientific misconduct despite widespread awareness of the problem.[25] Although other organizations exist to address problems relating to misuse of animals or humans in experimentation, radiation handling violations, and financial misconduct with research dollars, the advent of organizations that address other forms of scientific misconduct is relatively recent.

3.2.2 Definition of Research Misconduct

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

Finally, the definitions of misconduct are influenced by the legal structure of the countries in which they exist, the nature of the national body that has assumed the greatest responsibility for responding to the problem, and the ethical norms of the scientific community.

The definitional problem is exacerbated in countries in which multiple bodies have been involved in responding to the problem. For example, in Great Britain, the Association of the British Pharmaceutical Industry defines "research fraud" as the generation of false data with an intent to deceive, and the Royal College of Physicians defines "scientific misconduct" as piracy, plagiarism, and fraud.[1] In contrast, the MRC defines scientific misconduct as:

> fabrication, falsification, plagiarism, or deception in proposing, carrying out, or reporting results of research and deliberate, dangerous, or negligent deviations from accepted practice in carrying out research. It includes failure t o 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, which included 10 medical councils, professional societies, foundations and industry in the UK, led to a broader definition that states "Behaviour by a researcher, intentional or not, that falls short of good ethical and scientific standard."

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

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

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

[1] These terms are further defined as follows:
Piracy is the deliberate exploitation of ideas from others without acknowledgement. Plagiarism is the copying of ideas, data or text (or various combinations of the three) without permission or acknowledgement. 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.)

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

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

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

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

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

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

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

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

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

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

> [A]. Scientific dishonesty includes all deliberate fraudulent work at any time during the application-research-publication process as well as such extreme cases of negligence that the question of professional credibility becomes an issue. This corresponds to the legal concepts of intent and gross negligence.
>
> [B]. The area of scientific dishonesty that is covered by the DCSD is characterized by falsification or distortion of the scientific message or a false credit or emphasis given to a scientist. This includes but is not limited to:
>
> - construction of data
> - selective and hidden rejection of undesirable results
> - substitution with fictive data

- deliberate manipulation of statistics with the intention of drawing conclusions beyond what the data warrant
- distorted interpretations of results and distortion of conclusions
- plagiarism of other people's results or entire articles
- distorted representations of other scientists' results
- inappropriate credit as author
- misleading applications

Norway has an even broader definition of misconduct that was developed with significant input from the Danish experience. It is simply stated as,

"All serious deviation from accepted ethical research practices in proposing, performing and reporting research." It includes (1) fabrication and/or falsification of research results, (2) plagiarism of data or articles, (3) intended selection or withholding of results for publication when those results are relevant to the conclusion, (4) erroneous use of statistical or other methods, (5) intentional or gross negligence in withholding details in methods, (6) erroneous listing of authors, (7) erroneous presentation of research by other investigators, (8) presentation of research to the general public without scientific publication, and (9) unacceptable duplicate publication. The definitions used in Finland and Sweden are similarly broad.

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

Violations of human subject regulations would constitute scientific misconduct under the British, Canadian, and Danish models. Further, under the Danish and Australian systems, authorship disputes are investigated.[m]

3.2.3 The Investigation

As stated above, under most systems, the university or research institution has primary responsibility for investigating the allegations of misconduct and then reporting the results of the investigation to a national body. Whether and which US federal agency has the jurisdiction to address misconduct depends on whether and which federal agency 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, they 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. Thus far, only ORI findings have been appealed. The final step in the Public Health Service process may involve an appeal to an administrative law judge who may ask for scientific assistance. In the United States, only 2 cases heard by the final appeal body have included

[m] Reference 25, p 126, refer to Case No. 11 from the 1993 cases investigated by the Danish Committee on Scientific Dishonesty and Good Scientific Practice, and the Australian definition of "scientific misconduct."

a scientist.[26] 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."[27] 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 one case in Poland,[28] 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.

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. In addition to the multiplicity of definitions that exist in the United States, 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 the university investigations that were provided to them, are available with limited information masked. In contrast, the NSF does not provide the names of guilty individuals and those names are removed from its reports. Similarly, the Danish Committee on Scientific Dishonesty does not publish the names of scientists found to have committed scientific misconduct. Under the United Kingdom's MRC process, the scientific community, sponsors and other "interested parties" are informed of findings of misconduct.

3.2.5 References

1. European Science Foundation. The European Code of Conduct for Research Integrity. Available at: http://www.nsf.gov/od/oise/Code_Conduct_ResearchIntegrity.pdf (Accessed March 9, 2012).
2. Danish Agency for Science, Technology, and Innovation. Annual reports (in English). Available at: http://en.fi.dk/councils-commissions/the-danish-committees-on-scientific-dishonesty/publications. (Accessed March 9, 2012).
3. Marcus A. Dutch university investigating psych researcher Stapel for data fraud. Retraction Watch Blog, September 7, 2011. Available at: http://retractionwatch.wordpress.com/2011/09/07/dutch-university-investigating-psych-researcher-stapel-for-data-fraud/ (Accessed March 9, 2012).

4. Tilburg University Press Release. Prof. Diederik Stapel Suspended. September 7, 2011. Available at: http://uvtapp.uvt.nl/fsw/spits.npc.ShowPressReleaseCM?v_id=4082238588785510 (Accessed March 9, 2012).
5. Marcus A. Stapel inquiry widens to the University of Groningen, University of Amsterdam. Retraction Watch Blog, September 26, 2011. Available at: http://retractionwatch.wordpress.com/2011/09/26/stapel-inquiry-widens-to-the-university-of-groningen/ (Accessed March 9, 2012).
6. Marcus A. Stapel report finds faked data in at least 30 papers, possibly more. Retraction Watch Blog, October 31, 2011. Available at: http://retractionwatch.wordpress.com/2011/10/31/stapel-report-finds-faked-data-in-at-least-30-papers-possibly-more/ (Accessed March 9, 2012).
7. Marcus A. Science drops other shoe in Stapel case, retracts recent paper on chaos. Retraction Watch Blog, December 1, 2011. Available at: http://retractionwatch.wordpress.com/2011/12/01/science-drops-other-shoe-in-stapel-case-retracts-recent-paper-on-chaos/ (Accessed March 9, 2012).
8. Erasmus MC. Erasmus MC dismisses professor. Available at http://www.erasmusmc.nl/corp_home/corp_news-center/2011/2011-11/ontslag.hoogleraar/?lang=en (Accessed March 9, 2012).
9. Committee for the Investigation of Scientific Integrity, Erasmus MC, University Medical Center Rotterdam. Report Summary at 4-5. November 16, 2011. Available at: http://www.erasmusmc.nl/5663/135857/3397899/report_summary_investigation_integrity?lang=en (Accessed March 9, 2012).
10. Marcus A. Breaking news: Prolific Dutch heart researcher fired over misconduct concerns. Retraction Watch Blog, November 17, 2011. Available at: http://retractionwatch.wordpress.com/2011/11/17/breaking-news-prolific-dutch-heart-researcher-fired-over-misconduct-concerns/ (Accessed March 9, 2012).
11. The Report of the National Commission for the investigation of Scientific Misconduct. Available at: http://www.aqua.cl/files3/918b93_ISA%20ethics%20investigation%20Apr%202011_EN.pdf (Accessed March 9, 2012).
12. Good Scientific Practices and Procedures for Handling Misconduct and Fraud in Science. Available at: http://www.tenk.fi/en/good_scientific_practice/practice.html (Accessed March 9, 2012).
13. Australian Research Council. Research Integrity. Available at: http://www.arc.gov.au/general/research_integrity.htm (Accessed March 9, 2012).
14. National Health and Medical Research Council. Australian Research Integrity Committee Framework. Available at http://www.arc.gov.au/pdf/ARIC_framework_feb_11.pdf (Accessed March 9, 2012).
15. Council of Canadian Academies. Honesty, Accountability and Trust: Fostering Research Integrity in Canada. Available at: http://www.scienceadvice.ca/uploads/eng/assessments%20and%20publications%20and%20news%20releases/research%20integrity/ri_report.pdf (Accessed March 9, 2012).
16. Canadian Institutes of Health Research. Upcoming Consultation on the Tri-Agency Framework: Responsible Conduct of Research. Available at: http://www.cihr-irsc.gc.ca/e/44021.html (Accessed March 9, 2012).
17. Lock S, Wells F, eds. *Fraud and Misconduct in Medical Research.* London, England: BMJ Publishing Group; 1996.

18. COPE. Code of Conduct. Available at: http://publicationethics.org/files/u2/New_Code.pdf (Accessed March 9, 2012).
19. Stafford N. Polish Academy Is to Establish a National Commission on Research Ethics. Available at: http://www.english.pan.pl/index.php?option=com_content&view=article&id=335%3Apolish-academy-is-to-establish-a-national-commission-on-research-ethics&catid=15%3Anews&Itemid=1 (Accessed March 9, 2012).
20. Raman PS, Padma TV. Indian Scientists Call for Scientific Misconduct Body. Available at http://www.scidev.net/en/news/indian-scientists-call-for-scientific-misconduct-body.html (Accessed March 9, 2012).
21. Qiu J. Publish or perish in China. *Nature*. 2010;463:142-143.
22. Qiu J. Chinese Academy of Sciences Has Big Plans for Nation's Research. Available at: http://www.nature.com/news/2011/110324/full/news.2011.180.html (Accessed March 9, 2012).
23. Tatalovic M. A Tsunami of Plagiarism in Serbia, but Hardly Any Retractions. Available at: http://retractionwatch.wordpress.com/2012/01/03/a-tsunami-of-plagiarism-in-serbia-but-hardly-any-retractions/#more-5723 (Accessed March 9, 2012).
24. Marcus A. Another Hattori Retraction Over Reused Figure from Cardiology Pub. Retraction Watch blog. December 20, 2011. Available at: http://retractionwatch.wordpress.com/2011/12/20/another-hattori-retraction-over-reused-figure-from-cardiology-pub/#more-5568 (Accessed March 9, 2012).
25. 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.
26. Parrish D. Improving the scientific misconduct hearing process. *JAMA*. 1997;277(16):1315-1319.
27. Evans I. Dealing with research misconduct in the United Kingdom: conduct unbecoming: the MRC's approach. *BMJ*. 1998;316(7146):1728-1729.
28. Zawadzki Z, Abbasi K. Polish plagiarism scandal unearthed. *BMJ*. 1998;316:645.

(Authorship: Debra Parrish and Harvey Marcovitch took the lead in writing this section of the white paper on behalf of the CSE Editorial Policy Committee. Debra Parrish revised this section for the 2009 Update. Elizabeth Blalock and Debbie Parrish revised this section for the 2012 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 30, 2012.)

3.3 Reporting Suspect Manuscripts

This section will focus on suspect manuscripts that have been submitted to journals but not yet published. The section will review the issues of how a manuscript might come to be considered suspect, the steps that should be taken when misconduct is alleged, people or institutions the journal might notify about a suspect manuscript, and responsibility for investigating allegations of misconduct. Sample correspondence related to this topic is available on the CSE website.[1]

A number of cases involving allegations of misconduct and manuscripts have been reported. Cases also exist in which an allegation of 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 may serve as the basis of a misconduct allegation. In addition to the advice rendered by the Office of Research Integrity (ORI) and the National Science Foundation (NSF), the Committee on Publication Ethics (COPE)[2] provides advice to journal editors regarding the handling of suspect manuscripts.

3.3.1 Why Might a Manuscript be Considered Suspect?

Suspect manuscripts might be identified through any of the following means:

- Screening for image manipulation
- Recognizing the text or data from a prior (yet unpublished) submission
- Allegations by other sources, including co-authors, other colleagues
- Data appear too neat
- Parties involved in peer review recognize their own work submitted by another
- Parties involved in peer review recognize the text or data from routine literature review
- Google searching of portions of text
- Screening for plagiarism using detection software

3.3.2 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
- Co-authors
- Disaffected colleagues
- Third-party observers
- Editorial office staff
- Anonymous sources (refer to Section 3.3.8)
- Federal agency

3.3.3 What Should be Done When Misconduct is Alleged?

Addressing allegations of misconduct is a sensitive matter, and should be done with great care, as it can affect an author's career. In correspondence concerning allegations of misconduct, it is important that language be non-accusatory, yet clear. It may be helpful to set deadlines for responses. Sample correspondence is available on the CSE website.[1] In general, when a manuscript under consideration by a journal is identified as suspect, the following steps are taken:

- Suspend peer review (notify participants in objective language that review has been suspended).
- Review the allegations internally to determine if there is reason to pursue the allegation further.
- If the allegation is deemed worth pursuing, the editor may notify others as outlined in the subsection below.

3.3.4 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 may choose to notify some or all of the following parties:

- The submitting author
- All authors
- The institution that employs the author(s)
- The sponsor of or funding body supporting the study
- An agency with jurisdiction over an investigation of the matter (e.g., the ORI)

Some editors choose to notify the corresponding author of a problem with a manuscript as recommended by some of the COPE flow charts,[2] while others contact all the authors when misconduct has been alleged in a manuscript, as recommended by the ICMJE. Both approaches have advantages. The COPE approach identifies a potential problem without initiating the steps required in a misconduct investigation and it minimizes 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 and provide the corresponding author an opportunity to obtain records before a co-author can destroy them; since the corresponding author knows who is responsible for each component of the manuscript, communication with the responsible author should be sufficient without involving all authors. Limitations of this approach are that the corresponding author is not always the senior author and that it does not allow the other authors to know that their manuscript has been questioned and may be investigated.

Communicating with all authors has the benefit of allowing all the authors to police themselves and is the most transparent method. Editors following the ICMJE recommendation and contacting all of the authors when misconduct is alleged will likely receive a prompt response, but this approach potentially increases the risk that word of the inquiry might not be kept confidential or that one 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. Authors accused of misconduct may contact the journal office about a suspect manuscript as required by their institution,

funding agency, or ORI. 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. 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. Other, unaccused authors may provide such notice if an accused author hesitates to do so.

3.3.5 What to do if the Submitting Author's Response is not Satisfactory

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. However, 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. Relatively few editors opt to notify the relevant federal agency (where suspect manuscripts are supported by federal funding), because the jurisdiction of the agencies is often unclear when a manuscript is submitted and because the agencies will likely refer the matter back to the employing institution for investigation. Also, notification of a federal agency places the journal in the role of accuser and involves the journal in the misconduct investigation, regardless of whether it wants to participate.

An editor may instruct the author of a suspect manuscript to withdraw the submission. While this action may appear to end the problem for the current journal, the editor is effectively passing the issue on to the next (unsuspecting) journal and editor.

3.3.6 Who Investigates Allegations of Misconduct?

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. Simply contacting the submitting author's institution, employer, or funding body may trigger an investigation by these parties. If an investigation is pursued, journal editors may or may not be informed of the results of such investigations.

3.3.7 What Information Should be Provided During Investigations?

If an editor notifies an institution or federal agency of an alleged instance of misconduct, the editor should be mindful that providing any material that should be confidential may influence the institution's or agency's expectations and make it more difficult for the editor to withhold other confidential material as an investigation progresses. The initial letter to the institution or agency should provide a summary of the allegation. If the editor chooses to provide the actual message of accusation, however, the person who made the allegation needs to provide permission for the editor to do so.

3.3.8 Handling Accusations from Anonymous Sources

Sometimes an anonymous source accuses an author or group of misconduct, plagiarism, or other breech of publication ethics. Making such accusations without backing them up with sufficient scientific argument or thought is, in itself, unethical in that addressing these accusations consumes considerable time on the part of editors and editorial staff, may result in unnecessary or erroneous retractions or expressions of concern, and is potentially slanderous. The NIH Committee on Scientific Conduct and Ethics states "In order to bring a formal complaint, allegations of research misconduct must be made in writing and contain sufficient details to make clear the nature of the activity and a description of the facts, events, and circumstances that led to the allegation. The signed allegation document is sent to the Agency Intramural Research Integrity Official (AIRIO). The identity of the complainant may remain confidential unless the allegations lead to an inquiry."[3]

If editors/staff are notified of potential allegations of misconduct, whether or not the accusations are signed, editors/staff are obligated to look into the allegation. In the case of allegations that are not signed and are not backed by strong facts, editors have few facts to pursue the truth and cannot prove the allegations are true. If accusations are not signed, but backed by strong facts, such as proof that articles have been plagiarized as reflected by comparisons of articles with others in a public database, it is possible for editors and staff to corroborate misbehavior. In situations in which articles have been proven by such means to be plagiarized, editors may decide to publish notices of duplicate or plagiarized articles, noting that knowledge from public databases has revealed the breaches of publication ethics. Editors may be hampered in notifying authors, and imposing sanctions may not be appropriate, if addresses are out of date, authors are deceased, or authors can no longer be located.

3.3.9 References

1. Council of Science Editors. Sample correspondence. Available at: http://www.councilscienceeditors.org/i4a/pages/index.cfm?pageid=3335 (Accessed March 9, 2012).
2. Committee Publication Ethics (COPE). Flowcharts. Available at: http://publicationethics.org/resources/flowcharts (Accessed March 9, 2012).
3. National Institutes of Health. Office of the Director. A Guide to the Handling of Research Misconduct Allegations. Available at: http://sourcebook.od.nih.gov/resethicscases/NIH%20Misconduct2.pdf (Accessed March 9, 2012).

(Authorship: Debra Parrish took the lead in writing this section of the white paper on behalf of the CSE Editorial Policy Committee. Debra Parrish revised this section for the 2009 Update. Elizabeth Blalock and Patricia Baskin revised this section for the 2012 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 30, 2012.)

3.4 Digital Images and Misconduct

Detection and communication of possible inappropriate manipulation and fraudulent manipulation of image data is a sensitive issue. Therefore, due diligence of all involved is important. First, it is of the utmost importance that authors of a manuscript understand what image data manipulations are considered acceptable and do not engage in unacceptable or fraudulent image data manipulations. In this respect, it is recommended that all authors of a manuscript review images intended to support their manuscript against the original image data prior to submission of their manuscript for peer-review. In addition, it is recommended that authors report how image data were manipulated, even if the image manipulations are considered acceptable practice, or state that image data were not manipulated. Second, peer-reviewers need the appropriate experience to critically and constructively assess the quality and originality of image data associated with a given manuscript they peer-review. Third, journal editors hold responsibility to independently evaluate image data based on their own assessment and that provided by the peer-reviewers and should question authors and request additional information considerately as needed. This due diligence of all involved is important not only to publish accurate science, but also to avoid wrongful accusations (and associated consequences for the authors).

The Rockefeller University Press has defined two types of digital image–related misconduct: inappropriate manipulation and fraudulent manipulation. Inappropriate manipulation refers to adjustment of 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 image data that does affect 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 actually not there.

The ease of image manipulation in powerful applications like Adobe Photoshop® may tempt authors to adjust or modify digital image files. Authors have been using these applications for more than 10 years. 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.

Editors 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); authors must understand the boundary between acceptable and unacceptable manipulation.

3.4.1 Guidelines for Handling Image Data

Guidelines developed by The Rockefeller University Press have been published elsewhere.[1] Examples of different types of manipulation and image manipulation cases are available.[1,2] Examples of guidelines from other publishers can be found here:

Journal of Cell Biology[3]

Nature[4]

Proceedings of the National Academy of Sciences[5]

Science[5]

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 journals. An expanded set of ethical guidelines for the appropriate handling of scientific digital images is available on the website of the Office of Research Integrity[7] and discussed in detail by Cromey (2010).[8]

3.4.2 Procedure for Handling Guideline Violations

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.[9] Sample correspondence related to this topic is available on the CSE website.[10]

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 or inappropriate adjustments to brightness and contrast. For color images, more sophisticated adjustments to contrast using the "levels" slides may be necessary to reveal inconsistencies. Informative examples are provided by Rossner and Yamada (2004; Figure 6 in their article)[1] and by Cromey (2010; Figure 1 in his article).[8]

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 image data in a manuscript being peer reviewed or 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 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 Microsoft Office PowerPoint® to Adobe 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.

Handling misconduct. If a clear case of inappropriate manipulation is detected, the author should be requested to submit the figure in question with an accurate representation of the original image 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 image data from the author. However, if there is *any* possibility that the manipulation may be fraudulent, the journal editor should be alerted, and the *original* image 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,[11] 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.[2] One case of unfounded allegations of fraudulent image data manipulation has recently been reported in detail.[12]

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 (refer to Sections 3.1, 3.2, and 3.3). Misconduct can be reported either to an author's institution or to the ORI.[13] 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.

3.4.3 References

1. Rossner M, Yamada K. What's in a picture: the temptation of image manipulation. *J Cell Biol*. 2004;166:11-15.
2. Parrish D, Noonan B. Image manipulation as research misconduct. *Sci. Eng. Ethics*. 2009;15:161-167.
3. *Journal of Cell Biology*: Image acquisition and manipulation. Available at: http://jcb.rupress.org/misc/ifora.shtml#image_aquisition (Accessed March 9, 2012).
4. *Nature.* Image integrity and standards. Available at: http://www.nature.com/authors/editorial_policies/image.html (Accessed March 9, 2012).
5. *Proceedings of the National Academy of Sciences (PNAS).* Figure preparation. Available at: http://www.pnas.org/site/misc/iforc.shtml#ix (Accessed March 9, 2012).
6. *Science*. Resolution, file format, and modification of figures. Available at: http://www.sciencemag.org/about/authors/prep/prep_revfigs.dtl#format (Accessed March 9, 2012).
7. Office of Research Integrity. Online learning tool for Research Integrity and Image Processing. Available at: http://ori.dhhs.gov/education/products/RIandImages/default.html (Accessed March 9, 2012).
8. Cromey DW. Avoiding twisted pixels: ethical guidelines for the appropriate use and manipulation of scientific digital images. *Sci. Eng. Ethics*. 2010;16:639-667.
9. Committee on Publication Ethics (COPE). Flowcharts. Available at: http://publicationethics.org/resources/flowcharts (Accessed March 9, 2012).

10. Council of Science Editors. Sample correspondence. Available at: http://www.councilscienceeditors.org/i4a/pages/index.cfm?pageid=3335 (Accessed March 9, 2012).
11. 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 9, 2012).
12. Goldenring JR. Innocence and due diligence: managing unfounded allegations of scientific misconduct. *Acad. Med*. 2010;85:527-530.
13. The Office of Research Integrity (ORI). Available at: http://ori.dhhs.gov/ (Accessed March 9, 2012).

(Authorship: Michael Rossner took the lead in writing this section of the white paper on behalf of the CSE Editorial Policy Committee. Daniel Salsbury revised this section for the 2009 Update. Wim D'Haeze and Michael Roy revised this section for the 2012 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 30, 2012.)

3.5 Correcting the Literature

For a variety of reasons, correcting the literature is a critical part of the research enterprise. 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. The need for corrections may originate from honest error or from misconduct. Because of the breadth of the scientific culture, it is important to note that no single recognized method exists 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 3 organizations that have had extensive experience in this area: the National Library of Medicine (NLM), the International Committee of Medical Journal Editors (ICMJE), and the Committee on Publication Ethics (COPE).

The NLM is the largest medical library in the world; it serves millions of researchers through MEDLINE and develops policies in response to issues that surface in the biomedical publishing community. Its Fact Sheet[1] outlines how it handles corrections to the literature. The ICMJE Uniform Requirements,[2] which are endorsed by more than 1,000 journals, reflect the experiences of editors since 1978 and are updated regularly to address new issues in scientific publication. COPE, established in 1977 by medical journal editors and now with more than 7,000 members, provides retraction guidelines[3] and flowcharts[4] on best practices that include correcting the literature.

The information that these organizations provide offers the greater scientific community a useful framework for addressing issues related to correcting the literature.

The following sections examine current literature correction practices and provide definitions of important terms. Also included are an editor's list of correction considerations, an editor's list of elements and operations for corrections, and examples of language used for correcting the literature.

3.5.1 Definitions

One of the 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, journals do not apply the term *retraction* uniformly. Some journals use the terms *erratum* or *withdrawal* for a retraction, which can confuse the reader. This document uses the NLM definition as the standard for literature correction terminology. The NLM and other indexing organizations do not differentiate between articles that are being corrected because of honest error from those that are being corrected due to scientific misconduct.

The primary methods used for correcting the literature are *errata* and *retractions*, whereas *expressions of concern* are used to raise awareness to a possible problem in an article.

- ***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. Errata identify a correction to a small, isolated portion of an otherwise reliable article. The NLM and other indexing organization do not differentiate between errors that originate in the research process, such as errors in the methodology or analysis, and those that occurred in the publication process, such as typographical mistakes or printing errors. Editors should check with their indexing serves for instructions when they have errata related to author names and titles so that online searching issues can be properly addressed.

- ***Retractions.*** Retractions identify an article that was previously published and is now retracted through a formal issuance from the author, editor, publisher, or other authorized agent. Retractions refer to an article in its entirety that is the result of a pervasive error, nonreproducible research, scientific misconduct, or duplicate publication. A "retraction in part" or a "partial retraction" is more significant than an erratum. A "retraction in part" is the result of an incorrect section or a particular portion of an article that is incorrect, leaving the majority of the information and the article's stated conclusions uncompromised by the removal of that portion of the content. 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.[5] The expression of concern is a publication notice that is generally made by an editor to draw attention to possible problems, but it does not go so far as to retract or correct an article. An editor who has a significant concern about the reliability of an article but not enough information to warrant a retraction until an institutional investigation is complete will sometimes use an expression of concern.

3.5.2 Processes and Considerations

The incidence of literature corrections, whether in the form of errata or retractions, in biomedicine is low, but the numbers have been increasing.[6, 7, 8] Whether the increases are the result of heightened awareness, easier detection and notice of corrections, and/or better publication practices, there is good reason to prevent and minimize the need for them. Other sections of this document address these issues.

A variety of "authorized" agents correct the literature. They included authors, editors, publishers or journal owners, legal counsel, and representatives from the institution or organization where the work was produced (e.g., department chairpersons, deans, or laboratory directors). The NLM, ICMJE's Uniform Requirements, and COPE describe those persons from whom they will accept literature corrections.

Of the two 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 and "remove" (although not generally literally "remove") the article or part of the article from the scientific record. Admitting to a significant error, careless practices, unethical handling of the work on the part of one or more authors, or that the article resulted from their misconduct is difficult for authors to admit. However, retractions are most easily published when all authors agree to the need for the retraction and to the language in which the retraction is described. Following the list below, identifying the responsible party and reason for the error—whether or not it constitutes misconduct—are important elements of a thorough correction. It is not uncommon for authors to disagree about the language of an erratum or retraction, or whether to submit one at all. Such situations are delicate and vary in difficulty.

Below is information editors should consider regarding corrections to the literature and elements for corrections.

3.5.2.1 Editor's List of Correction Considerations

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 responsible author(s) should make the request. However, occasions when only some of the authors request and agree to a correction or when a third party must make the request arise when, for example, authors disagree or refuse to take responsibility for the correction. The editor's concern should be correcting the article so the readership can rely on the information published.

Who writes the correction? Depending on the situation, author(s) of the paper being corrected should make the literature correction. If there is disagreement, the correction should be written by a responsible institutional official or the journal 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. The text of the retraction should explain why the article is being retracted and include the full original citation.

When should the correction be published? A correction should be published as soon as reasonably possible. The decision when to publish a correction rests with the editor and may be complicated by many factors, such as differences of opinions among the authors; difficulty in locating authors; or unresponsive authors, institutions, or other editors.

When should a retracted article be removed from an online site? Unless an article poses serious health risk or legal implications, the article should not be removed. Instead, the article should be clearly marked as a retraction.

When is it acceptable to alter the HTML version of the published article? On occasion the published article, also known as version of record, is corrected. This is sometimes done if the correction is very minor or very significant. The "corrected version of record" should carry a note indicating that this version is different from the earlier published version, including the print if produced, and how it differs. Usually, the earlier online versions are not removed so that the history of versions can be obtained by readers. The online journal site, however, will point to the most recent version available as the result of a search.[9]

Is there a statute of limitations for the publication of errata and/or retractions? There are many questions that need to be considered. As an example, recent cases involved figure panel duplications that were identified in papers published more than 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 such a correction or retraction 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 10 years old? Does it matter if today's standards are different or more strictly enforced?

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 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 article and retraction? Is it appropriate for the editor of another journal to publish such a paper? These are questions for which editors do not have a unified response.

3.5.2.2 Editor's List of Elements and Operations for Corrections

Although best practices to correct the literature exist, variations in the style arise within the same discipline. However, when an erratum or a retraction is appropriate, it is desirable to consider the information outlined below when possible.

	Errata	Retraction	Expression of concern
Title	Samples include "Erratum: title of article requiring correction" "Correction: title of article requiring correction" "Correction for First Author Name et al., title of article requiring correction"	Samples include "Retraction: title of article requiring retraction" "Retraction notice to 'title of article requiring correction' [citation information]" "Withdrawal of the article of Last Author et al., 'title of article requiring retraction' [citation information]" "Partial retraction. title of article requiring retraction"	Samples include "Expression of concern: title of article of concern" "Editorial expression of concern for First Author Name et al., title of article of concern"
Text: what is being corrected or of concern	Yes		
Text: who is responsible for causing the correction or concern	Desirable but not always necessary	Yes	Generally not appropriate
Complete citation to the article being retracted	Yes		
Correction listed in the table of contents	Yes		
Printed on a numbered page (print publications)	Yes		
Published online ahead of print	Yes		
Corrections freely available online	Yes		
Link to the original article	Yes		
Link from the original article to the correction or expression of concern	Yes		
Alter HTML version of article being corrected	On occasion. Sometimes journals will make very minor corrections (e.g., addition of a corresponding author) or those that are very critical (e.g., dosage) but also note it in the formal erratum	No	No
Replace PDF of article being corrected with watermark stamp version noting correction	No	Yes. Stamp should note "Retracted" on each page and may include the date of the retraction	No
Remove the HTML version of the article.	No	Most journals leave the HTML version online but marked with a header and link to alert the reader	No
PDF of article being corrected to include the correction itself	Desirable but not a common practice	Yes	Yes
DOI	Yes	Yes	Yes

3.5.3 Examples of Errata, Partial Retractions, Retractions, and Expressions of Concern

Just as the policies for publishing literature corrections vary, the actual publication of the corrections varies as well. The following sections provide examples of literature corrections (errata and retractions) and "expressions of concern," along with 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.

3.5.3.1 Errata

- *PLoS ONE*. 2012. http://dx.doi.org/10.1371/annotation/ec04ad74-63cc-4fbe-9ad8-074a1d62fdf4. Erratum submitted by authors. Author added to byline.

  Correction: cAMP Response Element Binding Protein Is Required for Differentiation of Respiratory Epithelium during Murine Development

  An author was omitted from the author list. Richard Mollard should be listed as seventh author. His affiliation is Department of Biochemistry & Molecular Biology, Monash University, Clayton, Victoria, Australia. His author contributions are: Analyzed the data, wrote the manuscript.

  No competing interests declared.

- *Exp. Neurobiol.* 2011;20(3):137-143.

  Erratum: Neuroprotective Effect of Lucium chinense Fruit on Trimethyltin-Induced Learning and Memory Deficits in the Rats

  We would like to add an author and an acknowledgment as shown below. The added author's name and affiliation are marked by underlines.

  Hyun-Jung Park[1#], Hyun Soo Shim[2#], Woong Ki Choi[1], Kyung Soo Kim[1], Hyunsu Bae[3], and Insop Shim[2#*]

  [1]Basic Oriental Medical Science and Acupuncture and Meridian Science Research Center, Kyung Hee University, Seoul 130-701, [2]Department of Integrative Medicine and Research Center of Behavioral Medicine, College of Medicine, The Catholic University of Korea, Seoul 137-701, [3]Department of Physiology, College of Oriental Medicine, Kyung-Hee University, Seoul 130-701, Korea

  ACKNOWLEDGMENTS

  This research was supported by Ministry for Food, Agriculture, Forestry and Fisheries (110126-03-2-HD120), Republic of Korea."

3.5.3.2 Partial Retraction

- *Science*. 2011;334(6053):176. Partial Retraction submitted by authors.

  Partial retraction

  In our 23 October 2009 report, "Detection of an Infectious Retrovirus, XMRV, in blood cells of patients with chronic fatigue syndrome" (1), two of the coauthors, Silverman and Das Gupta, analyzed DNA samples from chronic fatigue syndrome (CFS) patients and healthy controls. A reexamination by Silverman and Das Gupta of the samples they used shows that some of the CFS peripheral blood mononuclear cell (PBMC) DNA preparations are contaminated with XMRV plasmid DNA (2). The following figures and table were based on the contaminated data: Figure 1, single-round PCR detection

of XMRV sequences in CFS PBMC DNA samples; table S1, XMRV sequences previously attributed to CFS patients; and figure S2, the phylogenetic analysis of those sequences. Therefore, we are retracting those figures and table.

R.H. Silverman, J. Das Gupta,[1] V. C. Lombardi, F. W. Ruscetti,[3] M. A. Pfost, K. Hagen, D.L. Peterson, S. K. Ruscetti, R.K. Bagni, C. Petrow-Sadowski, B. Gold, M. Dean, J.A. Mikovits

References and Notes

1. V. C. Lombardi, F. W. Ruscetti, J. Das Gupta, M. A. P fost, K. S. Hagen, D. L. Peterson, S. K. Ruscetti, R. K. Bagni, C. Petrow-Sadowski, B. Gold, M. Dean, R. H. Silverman, J. A. Mikovits, Science 326, 585 (2009).
2. Supporting online material showing there analysis is available at www.sciencemag.org/cgi/content/full/science.1212182/DC1. Published online 22 September 2011; 10.1126/science.1212182"

- *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 δ18O "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 δ18O 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.

(JU Baldini, F McDermott, IJ Fairchild)

References

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.

3.5.3.3 Retractions

- *J. Pharm. Sci*. 99:1535–1547. doi: 10.1002/jps.21888. Retraction agreed to by all authors, editor in chief, publisher, and scientific society.

  Retracted: Convulsant activity and pharmacokinetic–pharmacodynamic modeling of the electroencephalogram effect of gemifloxacin in rats.

  The following article from the *Journal of Pharmaceutical Sciences*, "Convulsant Activity and Pharmacokinetic–Pharmacodynamic Modeling of the Electroencephalogram Effect of Gemifloxacin in Rats," by Bikash Roy, Anirbandeep Bose, Uttam Bhaumik, Ayan Das, Nilendra Chatterjee, Animesh Ghosh, Soumendra Darbar, Amlan Kanti Sarkar, Pinaki Sengupta, and T. K. Pal, published online on 7 August 2009 in Wiley InterScience and subsequently on Wiley Online Library (wileyonlinelibrary.com), has been retracted by agreement between the authors; the journal's Editor in Chief, Ronald T. Borchardt; Wiley Periodicals, Inc.; and the American Pharmacists Association. The retraction has been agreed due to the inappropriate use of previously published work.

- *Proc. Natl. Acad. Sci. USA* 2006;103(50):19213. Retraction submitted by 2 editors-in-chief of different journals

  Retraction for Coldren et al., Flexible bilayers with spontaneous curvature lead to lamellar gels and spontaneous vesicles

  CHEMISTRY. For the articles "Flexible bilayers with spontaneous curvature lead to lamellar gels and spontaneous vesicles," by Bret A. Coldren Heidi Warriner Ryan van Zanten Joseph A. Zasadzinski and Eric B. Sirota, which appeared in issue 8, February 21, 2006, of Proc Natl Acad Sci USA (103:2524-2529; first published February 8, 2006; 10.1073/pnas.0507024103), and "Lamellar gels and spontaneous vesicles in catanionic surfactant mixtures," by Bret A. Coldren, Heidi Warriner, Ryan van Zanten, Joseph A. Zasadzinski, and Eric B. Sirota, which appeared in issue 6, March 14, 2006, of Langmuir (22:2465-2473), the editors of both journals retract these papers because they constitute duplicate publication.

  (SH Snyder, Senior Editor, PNAS, and DG Whitten , Editor-in-Chief, Langmuir)

- *Cancer. Res.* 2010;70:10485. Retraction submitted by some authors, 1 author not located, and 1 author disagreed with retraction.

  Retraction: Tripeptidyl-Peptidase II Controls DNA Damage Responses and In Vivo g-Irradiation Resistance of Tumors

  The authors retract the article titled "Tripeptidyl-Peptidase II Controls DNA Damage Responses and In Vivo g-Irradiation Resistance of Tumors," which was published in the August 1, 2007, issue of Cancer Research (1). The authors have been unable to reproduce the in vivo data of this article and the data concerning the requirement for PI3K-like kinases in the relocalization of TPPII in response to g-irradiation. Analysis of other data of this article could be continued by new experiments using modified protocols. They are presented elsewhere (2). The authors apologize for the confusion caused by the published data. Five of the 7 authors agreed to the retraction of this article; one author (Lu Lei) was unable to be located, and another author (Hong Xu) disagreed with the retraction of the article.

  (Rickard Glas, Steven Applequist, Rajender Naredla)

References

1. Xu H, Lei L, Kunert R, Naredla R, et al. TripeptidyI-peptidaseII controls DNA damage responses and in vivo gamma-irradiation resistance of tumors. *Cancer Res*. 2007;67:7165-7174.
2. Preta G, de Klark R, Glas R. A role for nuclear translocation of tripeptidyl-peptidase II in reactive oxygen species-dependent DNA damage responses. *Biochem. Biophys. Res. Commun*. 2009;389:575-579.

- *Blood.* 2012;119(7):1793. Retraction submitted by the corresponding author and the journal.

  Retraction. Mayack SR, Wagers AJ. Osteolineage niche cells initiate hematopoietic stem cell mobilization. *Blood*. 2008;112(3):519–531.

  "The corresponding author (Amy J. Wagers) and the journal wish to retract the 1 August 2008 paper cited above. Based on information discovered by the corresponding author after publication and reported by her to the journal in August 2010, which is now confirmed by a subsequent institutional investigation, this paper was found to contain duplicated data and other inappropriate manipulations. The corresponding author requests retraction of the paper in its entirety and apologizes to the reviewers, editors, and readers of Blood for any adverse consequences that may have resulted from the paper's publication. This retraction has not been signed by the first author (Shane R. Mayack), who maintains that the results are valid."

- *Virus Res.* 2004;106:83. Retraction submitted by the publisher with authors' agreement.

  Retraction of "Nuclear factor kappa B (NF-κB) dependent modulation of Epstein-Barr virus latent membrane protein 1 (LMP1) in epidermal growth factor receptor (EGFR) promotor activity"

  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*.

3.5.3.4 Expressions of Concern

- *Science.* 2010;327:144. Published Online December 17 2009. Expression of concern submitted by editor.

  Editorial expression of concern

  In the 9 October 2009 issue, *Science* published the Research Article "Reactome array: Forging a link between metabolome and genome" by A. Beloqui *et al.* (*1*). *Science* is publishing this Editorial Expression of Concern to alert our readers to the fact that serious questions have been raised about the methods and data presented in this article. The questions focus in particular on the synthesis of the dye-labeled metabolites that are central to the microarray technique. In addition, the spectroscopic data the authors cite in support of their claim were not posted to the Bangor University School of Biological Sciences Web site at the time of publication, despite the authors' indication in the Supporting Online Material that the data would be so posted. In response to inquiries from *Science*, the authors have provided new descriptions of the synthetic methods that differ substantially from those in their published article. Based on our original concerns and the authors' response, *Science* has requested evaluation of the original data and records by officials at the authors' institutions: These officials have agreed to undertake this task.

  (Bruce Alberts, Editor-in-Chief)

  Reference

  1. Beloqui et al. *Science* 2009;326:252.

- *Proc. Natl. Acad. Sci. USA.* 2003;100:11816. Expression of concern submitted by editors.

  Editorial expression of concern: Preferential repair of ionizing radiation-induced damage in the transcribed strand of an active human gene is defective in Cockayne syndrome

  Cell Biology. 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. USA* (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.

  The coauthor S.A.L. does not concur with this assessment and note of concern. Although coauthor P.K.C. cannot of her own knowledge dispute the stated concern with the TCR data, she attests that the conclusions from the paper are valid, based on subsequent work in several laboratories, including her own.

  (Nicholas R. Cozzarelli, *Editor*-in-*Chief*)

- Copublished in *Circulation*, *Circulation Research*, and *Hypertension*. (*Circulation*. 2012;125:e461.) Expression of concern submitted by chairperson of scientific publishing committee of association.

  It has come to the attention of the American Heart Association (AHA), in a public manner (1–3), that there are questions concerning a number of figures in several AHA journals' articles:

  Circ. Res. 2001;88:22-29

  Hypertension. 2001;38:367-372

  Circulation. 2002;106:2019-2025

  Hypertension. 2003;41:156-162

  Circulation. 2004;110:317-323

After reviewing these concerns, we have asked the institution, Kyoto Prefectural University of Medicine, to investigate the allegations. Until we learn the outcome, we feel it is best to post this Expression of Concern to alert our readers that concerns about these articles have been raised.

(MK Cathcart, PhD, Chairperson, AHA Scientific Publishing Committee)

References

1. http://abnormalscienceblog.wordpress.com/2011/11/27/matsubara-lab-in-japan-breathtaking-reuse-of-western-and- northern-blot-bands/#more-1026. Accessed March 5, 2012.
2. http://abnormalscienceblog.wordpress.com/2011/11/30/matsubara-lab-in-japan-breathtaking-reuse-of-histological- images-and-fragments-part-2/. Accessed March 5, 2012.
3. http://abnormalscienceblog.wordpress.com/2011/12/14/matsubara-lab-in-japan-anything-goes-part-3/. Accessed March 5, 2012.

- *Science* 2006;314(5799):592. Expression of concern submitted by editors that was then followed up with a retraction

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 that followed expression of concern submitted by some authors.

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."

(R. Michael Roberts, M. Sivaguru, H. Y. Yong)

Reference

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

3.5.4 References

1. 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 9, 2012).
2. International Committee of Medical Journal Editors (ICMJE). Uniform requirements for manuscripts submitted to biomedical journals. Available at http://www.icmje.org/ (Accessed March 9, 2012).
3. Committee on Publication Ethics (COPE). Retraction guidelines. Available at: http://publicationethics.org/resources/guidelines (Accessed March 9, 2012).
4. Committee on Publication Ethics (COPE). Flowcharts. Available at: http://publicationethics.org/resources/flowcharts (Accessed March 9, 2012).
5. Kotzin S, Chief, Indexing, MEDLINE; written communication, December 2004.
6. Budd JM, Coble ZC, Anderson KM. Retracted Publications in Biomedicine: Cause for Concern. ACRL Conference, Philadelphia, PA: 2011. Available at: http://www.ala.org/acrl/sites/ala.org.acrl/files/content/conferences/confsandpreconfs/national/2011/papers/retracted_publicatio.pdf (Accessed March 9, 2012).
7. Furman JL, Jensen K, Murray, F. Governing knowledge in the scientific community: Exploring the role of retractions in biomedicine. *Research Policy*. 2012;41(2):276-290.
8. Wager E, Williams P. Why and how do journals retract articles? An analysis of Medline retractions 1988 – 2008. *J. Med. Ethics*. 2011;37(9):567-570.
9. NISO/ALPSP Journal Article Versions (JAV) Technical Working Group. Journal Article Versions (JAV): Recommendations of the NISO/ALPSP JAV Technical Working Group. April 2008. NISO-RP-8-2008.

(Authorship: Mary Scheetz took the lead in writing this section of the white paper on behalf of the CSE Editorial Policy Committee. Heather Goodell, Emilie Marcus, and Tara Marathe revised this section for the 2009 Update. Diane Scott-Lichter revised this section for the 2012 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 30, 2012.)

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 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. Regardless of how an editor chooses to respond, it is a good idea to request that the reporter forwards their questions in writing to allow time to carefully prepare a response. Remember that the response may be quoted in subsequent news articles.

3.6.2 Legal Counsel

Legal counsel typically contacts 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. A lawyer may demand 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 may 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.

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 resorting 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 and/or fund the scientists have the 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. Daniel Salsbury and Patricia Baskin revised this section for the 2012 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 30, 2012.)

Council of Science Editors

10200 W. 44th Ave, Suite 304
Wheat Ridge, CO 80033
Phone: 720-881-6046
Email: CSE@CouncilScienceEditors.org
Web: www.councilscienceeditors.org