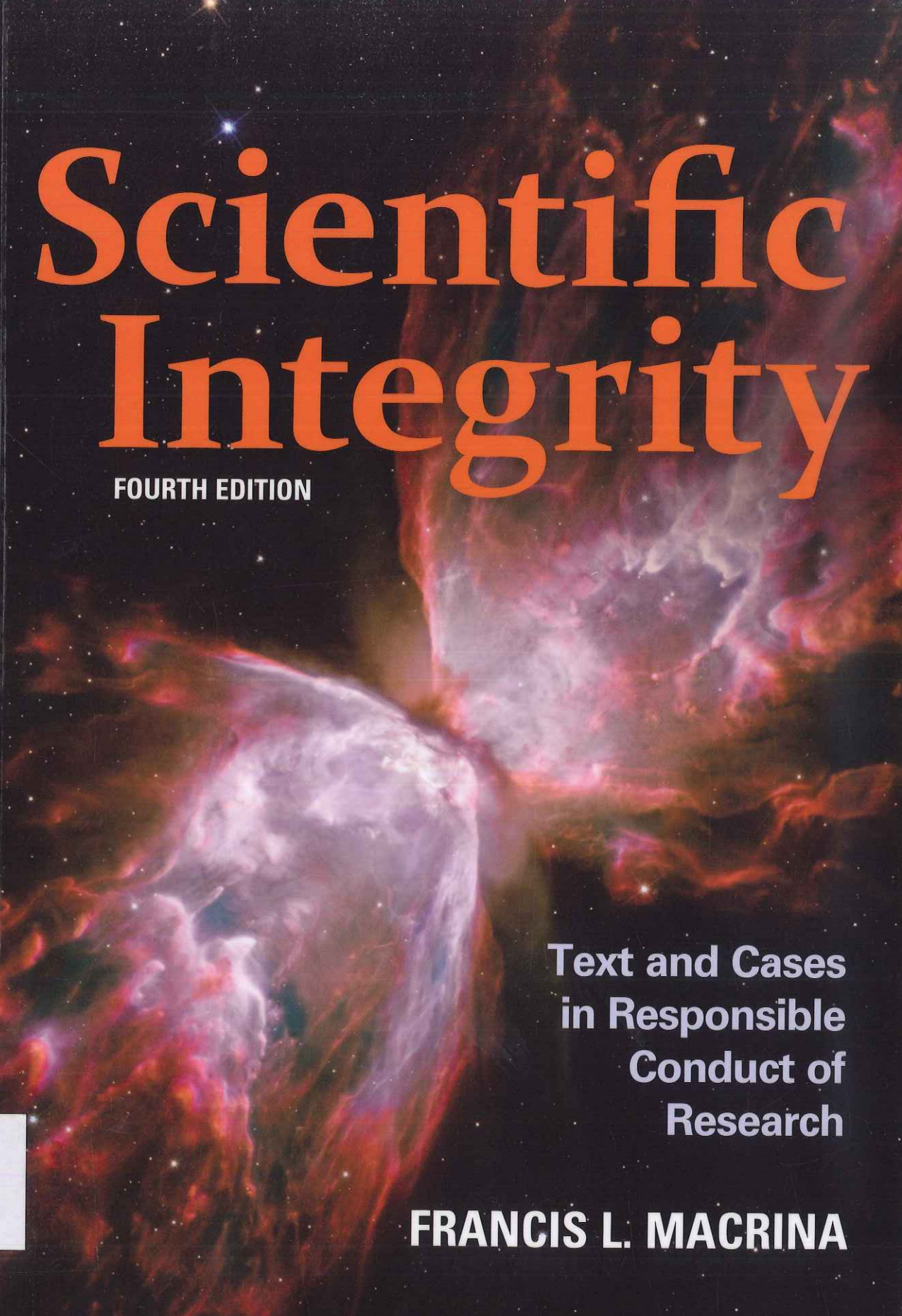
Scientific Integrity

FOURTH EDITION



Text and Cases in Responsible Conduct of Research

FRANCIS L. MACRINA

Compact between Biomedical Graduate Students and Their Research Advisors Web page:

https://www.aamc.org/initiatives/research/gradcompact/

At the Federation of American Societies for Experimental Biology (FASEB) website, the FASEB Statement on Including Postdoctoral Mentoring Plans in Research Grant Applications and Sample Mentoring Plans and Individual Development Plan for Postdoctoral Fellows:

http://www.faseb.org/Policy-and-Government-Affairs/Science-Policy-Issues/Training-and-Career-Opportunities-for-Scientists/Teaching-Advocacy-Material.aspx

At the National Postdoctoral Association (NPA) website, the NPA Postdoctoral Core Competencies Toolkit:

http://www.nationalpostdoc.org/competencies

Online resources from the American Association for the Advancement of Science (AAAS), including news, career advice, job opportunities, diversity issues, and a variety of other resources:

http://sciencecareers.sciencemag.org/career_magazine

myIDP, an interactive tool for creating an individual development plan, may be accessed at:

http://myidp.sciencecareers.org/

MinorityPostdoc.org is a Web portal on the minority postdoctoral experience:

http://www.minoritypostdoc.org/

National Action Council for Minorities in Engineering is a Web portal featuring resources in education and research for underrepresented minority students:

http://www.nacme.org/

The Council of Graduate Schools website presents a variety of print resources on mentoring and best practices in the responsible conduct of research:

http://www.cgsnet.org/

chapter 4

Authorship and Peer Review

Francis L. Macrina

Scientific Publication and Authorship • The Need for Authorship Criteria • Instructions for Authors • Authorship: Definitions, Duties and Responsibilities • Peer Review • Publication's Changing Landscape • Conclusion • Discussion Questions • Case Studies • Resources

Scientific Publication and Authorship

Publication of our experimental work in the peer-reviewed literature accomplishes several things. In addition to reporting new scientific findings, it allows evaluation of results and places them in perspective against a larger body of knowledge. Published work also credits other scientists whose contributions and ideas have been built upon. It also enables others to extend or repeat work by providing a description of experiments performed. In doing so, publication is the principal means for verifying the validity of our research results. The author's byline on our publications attributes priority and credit for the work and affirms who accepts responsibility for it. Finally, scientific publication provides the means to archive our research findings and to make them readily accessible over time.

The publication of research findings is frequently described as the "coin of the realm" in science, a terminology credited to sociologist Robert K. Merton. Although that phrase is now widely used to convey variously authorship or publication, Merton's intent had a deeper meaning. Specifically, his coin of the realm in science didn't just mean being an author of a publication or the publication itself. Rather, it was the associated recognition that followed from one's peers. Thus, publishing is the first step in securing the coin of the realm, but it's only in others appreciating and valuing the author's published work that recognition is earned. Throughout most of its six-edition history, Robert Day's book *How To Write and Publish a Scientific Paper* proclaims, "The goal of scientific research is publication."

Scientific Integrity: Text and Cases in Responsible Conduct of Research, 4th ed.
by Francis L. Macrina

doi:10.1128/9781555818487.ch4

In the 6th edition, Day and his coauthor, Barbara Gastel, posit that research as a profession is unique in that it *requires* that scientists write about what they do. Doing scientific research means you must report it. In commenting on scientific publication, Donald Kennedy says: "All the thinking, all the textual analysis, all the experiments, and the data gathering aren't anything until we write them up. In the world of scholarship we are what we write." It follows that we are either recognized or ignored by the perceived importance and the impact of our scholarly writing.

The peer-reviewed scientific literature

What is peer review? In this process, someone who is deemed to be knowledgeable in the subject matter of the reported research offers a written critique of a manuscript that has been submitted to a journal for publication. This is typically done anonymously and is overseen by an individual who has a formal relationship with the journal, e.g., an editor or associate editor. The reviewer may be an *ad hoc* volunteer or may be formally associated with the journal as well, e.g., an editorial review board member. The charge to peer reviewers varies across journals and publishers, but generally requires them to provide a critique on the originality and soundness of the work, the appropriateness of the detail in which it is presented, the sufficiency of the methodology, the degree to which interpretations and conclusions are supported by the data, and compliance with applicable standards of the research including ethics of experimentation and other research-specific issues (e.g, public data accessibility and plans for sharing research-related materials). Generally, reviewers' comments are meant to be seen by the authors of the paper, but sometimes they may be specifically directed only to an editor. Finally, the reviewer is usually expected to provide a recommendation to the editor that can range from accepting the manuscript for publication without modification to rejecting it. Dispositions along the spectrum created by these two extremes vary from recommending copyediting to performing additional experiments in support of the conclusions.

What does peer-reviewed literature look like? In practice, the time-honored image of bound journals on the shelves of library stacks or in departmental conference rooms has given way to the computer screen. Although printed journals are not likely to ever disappear, digital access to the peer-reviewed literature has become the norm. There are three platforms for digital scientific publication. The first involves digital copies of the corresponding print journals maintained by many publishers on their computer servers. For a personal or institutional subscription fee, the user accesses a publication and can read it online, save an electronic file copy, and print the paper if desired. For the cost of a subscription fee (borne by the reader or by a library site license), this puts the scientific literature no farther away than the end user's computer or handheld electronic device. A second form of digitally accessible scientific literature is called open access (OA) and comprises journals that are exclusively digital, with no printed counterparts. Access to them is free to the end user. Instead of the cost of publication being paid by subscription fees, the authors bear the cost of publication. A third form of published research literature is the electronic repository. Here, papers that have been previously peer reviewed and published are available for free, electronic access. Well-known repositories include PubMed Central and related cooperative initiatives, e.g., Europe PubMed Central and PubMed Central Canada. Operated by the National Center for Biotechnology Information, PubMed Central contains papers that report research that has been supported by grants from the National Institutes of Health (NIH).

Additional discussion on digital publication appears later in this chapter.

The pressure to publish

In academic settings, publishing helps scientists to successfully compete for grants and to achieve promotions, tenure, higher salaries, priority of discovery, and professional prestige. For these reasons, there is pressure to publish. Unfortunately, scientists may sometimes react to these pressures in ways that lead to questionable practices. The need for that "one more paper" to add to the progress report of a grant application (to get a grant award) or an employer's activity report (to get a raise) or the *curriculum vitae* (to get a job) creates pressure to publish. The competitive nature of scientific research creates a need to be "first." And establishing the priority of one's scientific contributions is accomplished through publication. This priority takes on additional significance when seeking intellectual property protection like a patent that would be vital to commercializing your research results. Papers also publicize research activities, allowing principal investigators to recruit new trainees and junior investigators to their groups.

The large number of scientific journals provides many options for submitting papers. Journal quality and reviewing standards vary, so there is always likely to be a place where research findings can be published. Indeed, the rapid growth in OA journals has contributed significantly to increasing publication options, and this has caused concerns for some over the quality of peer review. The pressures to publish have given rise to euphemisms that describe what sometimes happens in scientific publishing. "Salami science" refers to the publication of related results in "slices": data sets are split and published separately instead of being presented in a unified way. This practice increases the number of published papers from the same body of data, giving the impression of increased productivity. Another phrase used to describe a related practice is "the least publishable unit," the smallest amount of data that can be written as a manuscript and published. Some publications and editors may be contributing to these practices. Publication categories termed variously "Notes," "Short Communications," or "Preliminary

Reports" accept brief reports of important findings that are intended to stand their own. When editors and reviewers do not heed their journal's policies, such brief publication formats open the door to the "salami slicers" and the "reductionists." The ethics of publishing data in a way that maximizes the number of papers is open to debate. Most would argue that it is not inherently wrong and that scientists must have the freedom to publish how and what they see fit. However, the fragmentary nature of such publications sometimes makes them difficult to evaluate. They can mislead the reader and create confusion in the field by giving inappropriate emphasis to one piece of work. Finally, unjustified multiple publications put undue strain on the peer review process.

The Need for Authorship Criteria

Historically, the scientific community has relied on rather informal, often unwritten, and sometimes vague or ill-defined criteria for determining authorship on scientific papers. That approach has not served science well. It can breed misunderstanding, hard feelings, and confusion. However, beginning in the 1980s we have seen wide-scale and continuing change as institutions, societies, editorial boards, and publishers seek to clarify, define, and even codify the criteria used to assign authorship and its responsibilities. Funding agencies have also entered the fray, putting forth both ideas and policies that have an impact on publication practices.

Today in the biomedical sciences, single-authored research publications have become a rarity. Even at the most fundamental level—the training of students and postdoctoral fellows—the multiauthored paper is commonplace. Interdisciplinary approaches mandate collaboration. This makes multiauthorship the norm, and there is no expectation that the number of coauthors has to be limited. But, no matter the number, authors in the byline of a paper all have a stake in their published work. Defining that stake can be elusive, however, without rational guidelines.

Scientists agree that it would be wrong to include as an author on a paper someone who made no experimental, technical, or intellectual contributions to the work. Similarly, if someone thought of and performed a key experiment and provided an interpretation of the results, authorship for that person would be obligatory. These extremes have never really been in question. But decisions on authoring scientific papers frequently fall in between these examples. And the responsibilities of individuals whose names appear on multiauthored papers are not always clear, although this topic is increasingly debated. "If you are willing to take the credit, you have to take the responsibility" is a much-used statement that is not so simple to deal with in every case of coauthored scientific publication. To this end, conversations, guidelines, and policies on scientific authorship have been

increasingly evident in the past few decades. For example, the number of publications on the subject of authorship of scientific papers has jumped from a handful in the 1970s to thousands in the present day. Interrogation of the PubMed database using search terms like "authorship guidelines," "authorship criteria," "ghost authorship," and "honorary authorship" currently reveals a plethora of scholarly writing on the subject. A sampling of topic areas includes authorship responsibilities, ethical publication guidelines, management of errors in the literature, the prevalence of ghost and honorary authorship, and the impact of disclosure of competing interests on research reporting. Institutions and professional societies have implemented guidelines dealing with authorship and publication. And professional organizations and scholarly societies continue to study and make recommendations about authorship and publication practices.

Publication policies and guidance have grown in scope and number over the past few decades. They continue to evolve, and they merit the attention of novice and seasoned scientist-authors. The following two sections of this chapter will provide an overview of authorship best practices derived from a variety of such sources.

Instructions for Authors

The "Instructions for Authors" sections of scientific journals have become useful places to glean information on authorship and publication standards. Today, instructions for authors are typically available online at the journal's home page. These instructions provide the details of manuscript preparation required by the journal, its general policies, and often its philosophy of publication. These latter points, although different from journal to journal, are indeed standards for publication. Sometimes these issues are reaffirmed after the paper is submitted; for example, they may be stated in the letter acknowledging receipt of the manuscript, in the acceptance letter, or in other publication-related correspondence. Prospective authors should read and be familiar with the instructions for authors of the journal to which they intend to submit their work. In fact, consulting these instructions can assist in the decision on journal selection. Journal publishers often use this space to state the kinds of research considered appropriate for publication. This information, along with perusal of the published material that appears in the journal, helps with the decision on where to submit a paper. For novice authors, it is highly recommended to seek the advice of mentors and experienced colleagues on where to publish.

Details of manuscript preparation

Instructions for authors contain essential information needed to prepare and submit the manuscript. Details on format, space constraints, or word

limitations; preparation of figures; use of abbreviations and symbols; and proper chemical, biological, and genetic nomenclature are found there. For information on symbols and nomenclature, many journals use various authoritative reference books or guides as their accepted standards. Instructions for authors often contain housekeeping details such as procedures for submission of the manuscript—these days an electronic process—and charges associated with publication. (The lay public is often surprised to find that scientists must pay to publish their work in order to subsidize the cost of publication.) Finally, some journals provide guidance on the preparation of the various sections of the scientific paper: the abstract, introduction, materials and methods, results, and discussion.

Authorship criteria

Increasingly, journals provide guidance on the definition of authorship and its responsibilities. The words frequently come down to the same two issues. First, an author has to make a significant contribution to the work. Most statements like this leave plenty of room for interpretation and thus are flexible. Second, statements defining authorship may mention that all authors on a manuscript take responsibility for its content, or have read and approved the manuscript, or consent to its submission.

Some journals now require that the contributions of all coauthors be described in the paper, with this information usually published as a footnote. Such contributorship models may list author-associated activities like formulating hypotheses, experimental design, writing and critical editing, data collection and processing, analysis and interpretation, and literature review and citation. Additionally, the identification of the author or authors who take responsibility for the integrity of the work as a whole is sometimes encouraged (so-called guarantors of the work). The expectation is that these models reduce the ambiguity about the contributions of authors. This is arguable on the grounds that such disclosure does not allow assessment of the quality and quantity of contribution and is compounded by the usual brevity of description (e.g., "data acquisition"), which may add rather than remove ambiguity. On balance, however, the contributorship model is useful and meritorious because it demands that investigators who have a stake in the research be proactive in developing and defending the basis for their authorship.

Copyright

Copyright is a form of intellectual property that is defined by law in the United States and many other countries. In terms of a scientific manuscript, copyright means that an author or authors hold the right to duplicate (copy), distribute, display, or prepare a derivative version of the work. Copyright protects the expression of the creative work—the exact form of

text, figures, tables, etc.—but it does not protect the ideas or information conveyed in the manuscript. This is further discussed below and in chapter 9. Historically, a condition of manuscript acceptance for most scientific journals is that the authors assign the copyright to the publisher. Increasingly, print and online scientific journals are moving from this requirement by allowing the author(s) to hold copyright of the work while at the same time granting the publisher an exclusive license to publish the work. This facilitates the submission of published papers to repositories like PubMed and the ready posting of authors' published work to institutional and personal websites. OA publications use a variety of copyright models but often allow the authors to retain copyright while abiding by some type of an OA license that permits users to download, print, and use the content with appropriate attribution to the authors and the publisher. Whatever the copyright model, there is a required transaction in which the author(s) and the publisher form the legal agreement of copyright ownership and use. Finally, many journals require the authors to obtain permission to use any copyrighted material that is included in their manuscript, e.g., a diagram from a previously published paper. This is usually a formality that involves writing to the publisher who holds the copyright for the work to be included and describing its intended use. Many publishers have forms or online interactive sites that can be used in lieu of a letter. Of course, if the author holds the copyright under any of the models described above, this process is simplified.

Manuscript review

Matters relating to the peer review of the manuscript often are found in the "Instructions for Authors" section. Some journals allow authors to suggest the names of impartial reviewers, either *ad hoc* referees or members of the editorial board. This helps the editors do their job, and it is wise to take advantage of the opportunity. Who qualifies as an impartial reviewer? Opinions vary, and criteria are subjective. Often excluded as impartial reviewers are (i) people at the author's institution, (ii) people who have been recently associated with the author's laboratory, and (iii) the author's collaborators or coauthors. Individuals in the latter two categories are considered in view of the time that has elapsed since the author's last interactions with them.

Often a description of the peer review process is found in the instructions for authors. The process also may be described in a transmission (usually electronic) acknowledging receipt of the manuscript. Authors need to read about this process and know how it works. It can vary significantly for different journals. Understanding the process helps authors in dealing with the manuscript during peer review. The typical path of a manuscript through the review process is discussed later in this chapter.

Simultaneous submission, prior publication, and embargos on public disclosure

Submitting the same manuscript simultaneously to two or more journals is considered unethical. One assumes an author would do this to shorten the time from manuscript submission to print. In such a scheme, the intention is to publish in the journal that offers the quickest acceptance, thus accelerating reporting the research. At least three problems may emerge from this practice. First, the journal that published the paper becomes the default rather than the author's true choice, and this could affect the impact of research findings. Second, simultaneous submission puts an unfair burden on the peer-review and editorial processes. Finally, acceptance of the same manuscript by two or more journals could create copyright disputes that might have unwanted consequences for publishers and authors alike.

In 1968, the Council of Biology Editors (now called the Council of Science Editors) defined a "primary scientific publication" as follows:

> An acceptable primary scientific publication must be the first disclosure containing sufficient information to enable peers (1) to assess observations, (2) to repeat experiments, and (3) to evaluate intellectual processes; moreover, it must be susceptible to sensory perception, essentially permanent, available to the scientific community without restriction, and available for regular screening by one or more of the major recognized secondary services (e.g., Biological Abstracts, Chemical Abstracts, Index Medicus, Excerpta Medica, Bibliography of Agriculture, etc., in the United States and similar services in other countries).

Although today we'd add PubMed to the list of indexing services, the definition is relevant almost 50 years after it was first written. Precisely defining a primary scientific publication is important to the concept of prior publication.

In light of this definition, agreeing on what qualifies as prior publication is arguable. There is ambiguity when considering, for example, papers published in monographs (invited short papers or meeting proceedings). It is not easy to determine how "readily available" a source may be. How many copies of a monograph have to be sold or distributed to qualify it as available? If all copies of the monograph have been distributed in the United States, is it acceptable to submit essentially the same work to a journal published in Europe? Some argue that original work published in conference reports, symposium or meeting proceedings, or equivalent monographs is by definition preliminary owing to considerations of format and space. Often methods cannot be fully described, and such work is usually not subjected to peer review. However, if you are faced with a dilemma that impinges on the issue of prior publication, it is advisable to have a conversation with the editor of the journal to which you intend to submit your manuscript. Explaining the nature of the dilemma will provide disclosure to the editor or editorial staff that will yield an answer on how your particular situation should be handled.

Scientists generally agree that it is wrong to publish the same material as a primary publication in two different peer-reviewed journals. Using that philosophy as a guide is highly recommended. The Policy on Prior Publication of the *Proceedings of the National Academy of Sciences of the United States of America* (*PNAS*) provides additional clarity on the matter.

> PNAS considers results to have already been published if they have appeared in sufficient detail to allow replication, are publicly accessible with a fixed content, and have been validated by review. A paper has surely been published if it has appeared in a journal cited by any widely used abstracting service, whether in print or online, in English or in any other language. Gray areas result when two of the three criteria (replicability, public accessibility, and review) are met or only a portion of an article has appeared before. What if only one figure has been published previously? That need not doom subsequent publication in PNAS, but the authors must convince us at the time of submission that the figure is essential for the submitted paper yet not the major contribution.

Although their use was once limited to medical journals, embargo polices that control the release and the public presentation of in-press papers are now common in the scientific publishing world. Embargos prohibit the public release of information about a paper prior to a specific date. Typically they also include a date only after which the news media may report on the content of the paper. For example, an embargo may dictate that an in-press manuscript may be released to the news media no more than a week before the publication date and that news reports of the work not appear or be broadcast sooner than 24 hours before the publication date of the journal. An often-stated rationale in the medical publishing world is that this affords health care providers and their patients with concurrent access to the research findings. This enables the health care providers a window of time to assimilate the findings and be better prepared to answer patients' questions. Outside of this medical implication, general rationales for embargos include that they provide fair and equal access of scientific papers to the media and allow time for the media to develop well-informed commentary on the research.

Unpublished information cited in manuscripts

Some journals require proof of permission to cite the unpublished work of or communications from others. Information provided by a colleague as a "personal communication" may require a letter granting permission. The same is usually true for preprints or submitted manuscripts provided by your colleagues. Although a colleague may have provided a manuscript that has been submitted for publication, she may not feel comfortable

allowing that work to be cited in another paper before she knows that hers is accepted. By formally asking her permission, you eliminate any prospect of misunderstanding.

In the case of the author's unpublished work—"in-press" or "submitted" manuscripts—journals may require that copies of such manuscripts accompany the new submission so that they can be used if needed during peer review.

Sharing research materials

In natural science and biomedical journals it has become common for publishers to include statements about sharing research materials. This includes various research findings, or products including cell lines, microorganisms, mutants, plasmids, antibodies, and other biologicals and reagents. There are usually conditions stated for the release of such materials. For example, materials must be available at cost (e.g., preparation and shipping), they must be requested in reasonable quantities, and they must not be used for commercial purposes. Some policies are explicit in affirming that data sharing is done promptly and unconditionally. Journals may encourage that the paper denote which author or authors should be contacted to request published materials. Proper practice dictates that the materials be requested from that author or authors of the publication in which the material was initially described. For example, it is not acceptable to request a cell line from a third party, even though it may be convenient to do so. A novel cell line needed for work in Chicago may have been constructed by a scientist in Japan, but a colleague in a nearby city already has it. It is not appropriate to ask the stateside colleague to provide the cell line. Ask the Japanese investigator who made it and published the results. At the very most, you could suggest that he allow you to get a culture from your conveniently located neighbor.

Data sets associated with scientific manuscripts fall under the umbrella of data sharing as well. Also included in many instructions for authors is the requirement that authors deposit specialized data—e.g., nucleic acid and protein sequences, genomic and proteomic data, microarray data, structural studies data, and functional magnetic resonance imaging studies—in appropriate databases. Sharing research materials and proper deposition of results into databases are widely listed as conditions of publication.

Other kinds of data that may be prescribed for deposition in public repositories include climate data, ecological data, rare specimens, and fossils.

Conflict of interest

The disclosure of personal interests, activities, and associations has become a common required practice in the publication of scientific papers. Journal policies focus on the disclosure of any association with the potential to create a financial conflict of interest that might have an impact on

the paper. Of primary concern is that a financial interest of an author might give rise to bias or the perception of bias in the collection, analysis, or interpretation of the data reported in the manuscript. Simply disclosing the nature of the potential conflict provides the reader with a perspective that better affords the evaluation of the manuscript's findings and their interpretation. Financial conflicts may revolve around associations that connect the author or authors with a corporation whose products or services could be affected by the paper. Consider, for example, a paper that reports positively on a medical device, enhancing the perception of its reliability. There are several ways a financial conflict of interest might be created in such a scenario. These could include the following: (i) the company provided a grant to the author to do the research; (ii) the author is a paid consultant to the company; (iii) the author is a member of an advisory committee or the board of directors of the company; (iv) the author regularly gives public lectures or provides other services that are paid for by the company; (v) the author owns significant equity in the company; and (vi) the author receives royalty payments from the company for an invention that has been licensed to the company by the author and/or the author's institution.

Reporting associations that represent conflicts is done variously by publishers. In many cases this information is included in the manuscript, but sometimes the submission of such disclosures is also done using an electronic interface or data entry form. Journals may also require that potential conflicts of interest be reported by their editors, editorial boards, and reviewers. This information may be used to guide editorial and reviewer assignments. Some journals announce that none of their editors have relationships with corporations relevant to the subject matter of the journal, thus minimizing if not removing them from issues of conflict of interest as they relate to the peer review process. Author-declared conflicts usually appear in a footnote in the published paper.

Subjects protection in research

Some journals require an affirmation regarding the use of humans or animals in the work reported in the submitted manuscript. This may be a statement by the authors that institutional approval was sought and obtained from an institutional review board (see chapter 5) or the Institutional Animal Care and Use Committee (see chapter 6). Some journals require the inclusion of a statement that accepted practices or codes were followed in the conduct of the research. Some journals mention that a statement confirming that informed consent was obtained from human subjects must be included in the manuscript. Approval dates on either human or animal subjects protocols may have to be provided as well. Other human subject-related requirements that may be found in instructions for

authors relate to subject privacy and include reminders to strip identifying data from subject-derived materials or data; at least one journal requires the use of a consent and release form that must be signed by the subject if he or she could be recognized from an image or other published content.

A significant number of journals that publish the results of clinical trials require that they be registered in an accepted clinical trial registry (e.g., ClinicalTrials.gov, a site provided by the NIH) before the first subject is enrolled in the study. This practice was initiated in 2005 by the International Committee of Medical Journal Editors (ICMJE), thus making it a requirement for the hundreds of journals that used the ICMJE's Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. In 2007, the U.S. Food and Drug Administration enacted a federal law requiring that "applicable" clinical trials be registered on ClinicalTrials.gov. It also required the submission and posting of results on the website. The origin of this policy revolved around highly publicized cases of selective data reporting or suppression of clinical trials data that would otherwise reflect negatively on the research sponsor's product. The rationale for registration was grounded in the expectation that full disclosure of a clinical trial protocol will announce its existence, afford a comprehensive understanding of its features and characteristics, and, in doing so, reduce the chances of concealment or suppression of data when the results of the clinical trial are submitted for publication and, ultimately, published. The benefit of such registration has also been argued in terms of the public having access to clinical trials, thus providing them with information on available clinical trials that may be of direct interest to them, their families, or their friends.

Digital image integrity

The Rockefeller University Press, publisher of three biomedical journals, was a leader in developing policies that govern the handling of digital images submitted for publication. Publishers of many other journals have followed suit, and their instructions for authors describe both acceptable and unacceptable practices for dealing with digital images including gels, micrographs, specimen photographs, and other digital data. Implicit in these policies is that any digital image is data itself and should not be fundamentally changed. The Rockefeller University Press policy on digital image handling has been adapted or modified by many journals, and a summary of central elements most commonly found in such polices is as follows.

No specific feature or portion of the image may be enhanced, obscured, moved, removed, or introduced.

The creation of composite images (e.g., independently obtained images grouped together using editing software) must be explicitly indicated by some visual means (e.g., borders or dividing lines) and explained in the legend to the figure.

Adjustments made to brightness, contrast, or color are acceptable only if they are made to the entire image (not part of it) and if they do not have any effect on the information contained in the original image.

Some journals include methods for monitoring and enforcement in their policies. This may include general or random screening of digital images for manipulation using software programs or methods for detecting author-created modifications. Undisclosed, deliberate modification detected by these methods may result in the rejection of the paper and possibly in the notification of the author's institution or the funding agency that supported the research.

Biosecurity

Prompted by the 2001 bioterrorism attacks in the United States, the U.S. National Academy of Sciences and the U.S. Center for Strategic International Studies sponsored a 2003 meeting of editors, scientists, and security experts to discuss scientific publication and national security. From this meeting came a position paper authored by a group of editors and authors that concluded that certain scientific information should not be published because of its risk of use by terrorists.

The position paper was simultaneously published in *Nature*, *Science*, *PNAS*, and the journals of the American Society for Microbiology. It contained four concepts: (i) the integrity of the scientific process must be protected by publishing high-quality manuscripts written in sufficient detail to ensure reproducibility; (ii) there should be a commitment to deal responsibly and effectively with safety and security issues that may be raised by papers submitted for publication, and to increasing capacity to identify such issues as they arise; (iii) there is need for consideration and implementation of the appropriate level and design of processes to accomplish effective review of papers that raise such security issues; and (iv) the recognition that, on occasion, an editor may conclude that the potential harm of publication outweighs the potential societal benefits. Under such circumstances, the paper should be modified or not be published. In keeping with these concepts, the statement declared that journals and scientific societies can play an important role in encouraging investigators to communicate results of research in ways that maximize public benefits and minimize risks of misuse.

Since that time, a limited number of editorial boards and publishers have included language in their instructions for authors or editorial policies that addresses the issue of biosecurity in the peer review process. Such issues are typically broached under the rubric of "dual-use research of

concern" (DURC), which, for our purposes, may be defined according to the Office of Biotechnology Activities of the NIH as

> 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, agricultural crops and other plants, animals, the environment, or materiel.

In general, the language found in the publication policies or instructions for authors on biosecurity shares some common elements. Some journals state the expectation that the authors notify the editor if the manuscript being submitted reports findings that represent DURC. Policies typically affirm that the editor, editor-in-chief, or editorial board will evaluate the potential of DURC but that outside reviewers or experts may be consulted in making a decision about the manuscript. Finally, the language usually contains an implicit or explicit message that a manuscript may be turned down for publication based on biosecurity concerns.

Publication policies on biosecurity issues are found in multidisciplinary journals, like *Science*, *Nature*, and *PNAS*; and discipline-specific journals, like all of the journals published by the American Society for Microbiology and all of the journals published by the American Phytopathological Society. In general, however, the number of biomedical and life sciences journals that have dual-use peer review policies in place remains low more than a decade after the events that prompted their genesis. A 2011 survey report by David Resnik, Dionne Barner, and Gregg Dinse indicated that of 155 journals responding to a question of whether they had a written dual-use review policy, only 7.7% (about 12 journals) indicated that they did.

Finally, invoking security concerns within the context of the openness of biomedical research publication has engendered debate in scientific, publishing, and government circles. While some argue that the research enterprise is acting responsibly in monitoring and intervening in the publication of information with dual-use potential, others contend that this is blatant censorship.

Miscellanies

Some journals also include policies on the handling of disputes once papers are published. Occasionally, journals are explicit about the option of having their editors examine original data in the process of dispute resolution. In addition, many journals describe policies for publishing corrections of author errors (corrigenda), errors made by the journal (errata), or retractions of papers owing to invalid results. Publishers of a number of journals have also begun using text-similarity software programs to detect plagiarism. As part of journal policy, selected submissions may be screened against a large database of published papers. Plagiarized material found in a submitted manuscript requires correction. More preemptive action may

be necessary if the plagiarism rises to the level of research misconduct, copyright infringement, or both. Plagiarism detected in a published paper can result in the paper being retracted by the journal. Some journals allow plagiarism analyses of manuscripts to be done by the submitting author on a voluntary basis. This allows the author to make needed corrections before the paper is subjected to peer review. Such voluntary review might uncover self-plagiarism, which otherwise might be flagged by a journal-initiated plagiarism screen. If the author was not comfortable with the level of identical text discovered in the screen, this could be corrected or explained prior to the manuscript entering the peer review process.

Instructions for authors and editorial policies continue to evolve in response to external factors including new discoveries and knowledge, new technology, and the implementation of new or modified laws and policies. A recent example is the emergence of publication policies bearing on the issue of cultured cell line contamination and misidentification. Such problems result in wasted time and resources and can impede scientific progress. The journals published by the American Association for Cancer Research have adopted a policy requiring that submitted manuscripts must contain information on the origin of cell lines used in the research. Specifically, the origin of the cells and the date they were obtained must be disclosed, along with whether the cells were tested and authenticated. The method by which the cells were tested must be provided, including the last time such testing occurred. The National Institute of Standards and Technology (NIST) has launched a project to aid in cultured cell line authentication. NIST is in the process of collecting and cataloguing such DNA sequence data that will permit precise cell line identification based on the profiling of short tandem repeat sequences. The NIST project aims to collect DNA identification data for up to 1,500 human cell lines. These data will be posted in a public database at the National Center for Biotechnology Information for use by researchers in cell line authentication. Short tandem repeat profiling of animal (mouse and monkey) cell lines is also being developed and can be expected to expand the scope of molecular identification methods that can be used to authenticate cultured cell lines. Thus, it is reasonable to expect that publication policies on cell line authentication will be refined and adopted by other journals in the future.

Authorship: Definitions, Duties, and Responsibilities

Defining authorship

Criteria for authorship have been presented variously in journal policies, institutional guidelines, and professional society statements. Commonly invoked is the need for an author to have made a significant contribution to the

work. Such contributions are frequently described as those that have an effect on the "direction, scope, or depth" of the research. They have also been stated in terms of "conceptualization, design, execution, and/or interpretation" of the research. The development of necessary methodologies and data analysis essential to the conclusions of the project are also sometimes listed as contributions that justify authorship. Sometimes the language is specific, and contributions to the project are linked to having a "clear understanding of its goals." This leads to the issue of responsibility. Some have addressed this issue in defining authorship by invoking the need "to take responsibility for the defense of the study should the need arise" or "to present and defend the work in context at a scientific meeting." The challenge of coauthor responsibility where disparate contributions have been made was addressed in one case by saying that exceptions to this rule will need to be made when "one author has carried out a unique, sophisticated study or analysis." In other words, in certain collaborative studies, it may not be possible for every author to be able to rigorously present and defend all aspects of the work.

To illustrate the specificity and detail of authorship definitions, let's use two examples. First, let's examine the widely used definition of the ICMJE. This definition is found in the ICMJE's Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals, which were first published in 1979. Several updated versions of the Recommendations have appeared since that time. At present these Recommendations are used, in whole or in part, by more than 1,000 medical and biomedical journals.

The current ICMJE definition (August 2013) for authorship found in the Recommendations has, at its core, the following elements.

> The ICMJE recommends that authorship be based on the following 4 criteria:
>
> 1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
> 2. Drafting the work or revising it critically for important intellectual content; AND
> 3. Final approval of the version to be published; AND
> 4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Further guidance on authorship is offered by the ICMJE Recommendations in connection with these four criteria. Notable narrative includes the following.

> In addition to being accountable for the parts of the work he or she has done, an author should be able to identify which co-authors are responsible for specific other parts of the work. In addition, authors should have confidence in the integrity of the contributions of their co-authors. . . .

> These authorship criteria are intended to reserve the status of authorship for those who deserve credit and can take responsibility for the work. The criteria are not intended for use as a means to disqualify colleagues from authorship who otherwise meet authorship criteria by denying them the opportunity to meet criterion #s 2 or 3. Therefore, all individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript.
>
> The individuals who conduct the work are responsible for identifying who meets these criteria and ideally should do so when planning the work, making modifications as appropriate as the work progresses. It is the collective responsibility of the authors, not the journal to which the work is submitted, to determine that all people named as authors meet all four criteria; it is not the role of journal editors to determine who qualifies or does not qualify for authorship or to arbitrate authorship conflicts. If agreement cannot be reached about who qualifies for authorship, the institution(s) where the work was performed, not the journal editor, should be asked to investigate. If authors request removal or addition of an author after manuscript submission or publication, journal editors should seek an explanation and signed statement of agreement for the requested change from all listed authors and from the author to be removed or added.
>
> The corresponding author is the one individual who takes primary responsibility for communication with the journal during the manuscript submission, peer review, and publication process, and typically ensures that all the journal's administrative requirements, such as providing details of authorship, ethics committee approval, clinical trial registration documentation, and gathering conflict of interest forms and statements, are properly completed, although these duties may be delegated to one or more coauthors. The corresponding author should be available throughout the submission and peer review process to respond to editorial queries in a timely way, and should be available after publication to respond to critiques of the work and cooperate with any requests from the journal for data or additional information should questions about the paper arise after publication. . . .
>
> When a large multi-author group has conducted the work, the group ideally should decide who will be an author before the work is started and confirm who is an author before submitting the manuscript for publication. All members of the group named as authors should meet all four criteria for authorship, including approval of the final manuscript, and they should be able to take public responsibility for the work and should have full confidence in the accuracy and integrity of the work of other group authors. They will also be expected as individuals to complete conflict-of-interest disclosure forms.

Finally, contributions that do not merit authorship are mentioned in the ICMJE Recommendations:

> Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be acknowledged. Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are acquisition of funding; general supervision of a research group or general administrative support; and writing assistance, technical editing, language editing, and proofreading.

Now, let's look at the current definition found in the information for authors for *PNAS*.

> **Authorship** must be limited to those who have contributed substantially to the work. The corresponding author must have obtained permission from all authors for the submission of each version of the paper and for any change in authorship.
>
> All collaborators share some degree of responsibility for any paper they coauthor. Some coauthors have responsibility for the entire paper as an accurate, verifiable report of the research. These include coauthors who are accountable for the integrity of the data reported in the paper, carry out the analysis, write the manuscript, present major findings at conferences, or provide scientific leadership to junior colleagues. Coauthors who make specific, limited contributions to a paper are responsible for their contributions but may have only limited responsibility for other results. While not all coauthors may be familiar with all aspects of the research presented in their paper, all collaborators should have in place an appropriate process for reviewing the accuracy of the reported results. Authors must indicate their specific contributions to the published work. This information will be published as a footnote to the paper. Examples of designations include:
>
> - Designed research
> - Performed research
> - Contributed new reagents or analytic tools
> - Analyzed data
> - Wrote the paper
>
> An author may list more than one contribution, and more than one author may have contributed to the same aspect of the work.

Both the ICMJE and *PNAS* authorship definitions include many of the same elements. The ICMJE definition is specific in its conditions and how they are to be applied. The *PNAS* definition mentions the requirement for a substantial contribution and then ties this to examples later in its narrative. The *PNAS* definition is more explicit in detailing authorship responsibility and accountability when multiple authors are involved. Both definitions acknowledge that some coauthors may make specific contributions to the work and are responsible for them. The *PNAS* definition is explicit in affirming that some coauthors have responsibility for the entire paper (the guarantorship model), while the ICMJE definition embraces the use of the guarantorship model in language preceding the definition in the Recommendations. Aspects unique to the ICMJE definition involve an accommodation of multicenter-based, group-authored papers (often clinical trials fit this description). Both definitions address author accountability, equating this to the responsibility for authors in the byline to present the reported research finding in a public setting.

In summary, the ICMJE and *PNAS* authorship definitions provide a foundation for appreciating the evolving field of policies and practices

related to authorship. They cover a breadth of scientific disciplines, are updated regularly, and are, by and large, usefully explicit. Readers should be aware of other organizations (e.g., World Association of Medical Editors) and scientific societies (e.g., American Chemical Society, Society for Neurosciences, American Psychological Association, and American Society for Microbiology) that provide a rich array of information on authorship and publication practices. Most importantly, authors should rely on the instructions for authors of the journals in which they plan to submit their manuscripts.

Classifying authors

Although there is not a universally accepted authorship nomenclature, adjectives are commonly used to describe authors or types of authorships. Instructions for authors and general guidelines and policies may refer to these, thus providing context. Here is a synopsis of some of the more commonly used authorship terminology.

The senior author. Guidelines often define this person as the principal investigator, leader of the group, or laboratory director. If the byline of a paper lists a faculty mentor along with two of her predoctoral trainees and one postdoctoral trainee, then the mentor is the senior author. The senior author may be the first author listed in the byline. Most agree that the first author is defined as having played a major role in generating the data, interpreting the results, and writing the first draft of the manuscript. In many cases, however, the first author and the senior author are different. When this is so, it is customary in many disciplines for the senior author's name to be last in the byline.

Guidelines often vest senior authors with overarching responsibilities. What follows is an amalgamation of the typical responsibilities listed in several documents from universities, research institutions, professional societies, and publishers.

- The senior author, along with the first author, typically decides who else will be listed as coauthors. General criteria for making these decisions are discussed below. The senior author is responsible for notifying all coauthors of this decision and for facilitating discussion and decision making about the order of appearance of the coauthors' names in the byline.
- The senior author, usually with the help of the first author and sometimes other coauthors, decides on the people to be listed in the "Acknowledgments" section of the paper. The senior author should notify the individuals to be acknowledged. The senior author also is responsible for listing in the acknowledgments all sources of

financial support for the work. In short, the senior author is responsible for appropriately acknowledging all contributions to the work reported in the paper.

- Senior authors often are the guarantors of the work, as defined previously in the guarantorship model. This means they review all data contained in the paper and, in doing so, assume responsibility for the validity of the entire body of work. This assertion may present problems in regard to specialized work that may be outside the senior author's area of expertise. In such cases, one means of handling this is for the senior author to gain a reasonable understanding and verification of the data from the appropriate coauthor. Still, this problem persists as interdisciplinary research abounds and researchers from highly technical and specialized fields collaborate and copublish their results. Nonetheless, some of the guidelines in effect today are very specific on this point: the senior author must "understand the general principles of all work included in the paper."
- The senior author has a responsibility to facilitate communication among coauthors during the preparation of the manuscript. This means reviewing raw data and discussing new ideas for additional work. It certainly means reaching agreement on the part of all coauthors as to interpretation of results and conclusions.
- The senior author makes sure that the logistics of manuscript submission are properly followed. This may be something the senior author does directly or assigns to another author (see the sections on the first author and submitting author, below). Such things as manuscript format and related material and local editorial review (if required) are included here. Also included are all dealings with the publisher, e.g., correspondence, execution of copyright assignments and authorship agreement forms, and, where appropriate, financial matters such as publication charges.
- The senior author usually coordinates and oversees the responses to the peer reviewers' comments if the manuscript has to be revised. This may a task done collaboratively with or assigned to the first author, if they are not one and the same. He or she is responsible for involving the coauthors in this process as appropriate and for seeking the approval of all coauthors to submit the revised manuscript.
- The senior author is responsible for acting on and honoring requests to share materials from the research once the paper is published. Again, these may be assigned by the senior author to another person in the author byline. Some publication guidelines recommend that the person or persons to contact for materials reported in the paper be listed explicitly, usually in the "Materials and Methods" section of the paper. The senior author is responsible for coordinating and making responses to general inquiries or challenges about the work. The senior author assumes responsibility in dealing with the publication of corrections, errata, or retractions. This includes coordinating preparation of such items by seeking the comments and agreement of all coauthors. Finally, the senior author is responsible for the appropriate retention and storage of all data used to prepare the manuscript.

The first author. The first author is the author whose name appears first in the byline of the paper. As mentioned above, the first author is the person who participated significantly in the work by (i) doing experiments and collecting the data, (ii) interpreting the results, and (iii) writing the first draft of the manuscript. Some journals allow the first authorship position to be shared. In other words, if the contributions of two authors (or more in some journals) are equal or indistinguishable, then it is possible to identify each in the byline (e.g., with an asterisk) with a notation to that effect. Because there still is a linear order of names in the byline, the order of the equal contributors is left to authors' mutual decision. James Watson and Francis Crick reportedly used a coin toss to determine author order in their 1953 classic paper proposing the double-helical structure for DNA. Footnotes in contemporary papers reveal that the coin toss methodology has been used in reconciling shared first authorship.

The submitting author. The submitting author is usually the author who sees the manuscript through the submission process, e.g., letter writing, coordinating responses to the editor, responding to peer review comments. Sometimes this person is called the corresponding author. This may be the senior author, but it can be the first author. For example, a mentor (senior author) may want his postdoctoral fellow (first author) to gain experience in dealing with the peer review process. It should be remembered that certain responsibilities will fall on this author (see above). Many publishers indicate the submitting author on the first page of the published article. The responsibilities of the senior author with respect to correspondence after publication will then fall on the submitting author. When the submitting author and the senior author are not the same person, there should be a clear understanding of how follow-up correspondence related to the manuscript will be handled.

Other coauthors. Coauthors whose names appear between the first and last author in the byline of a paper are usually determined by the senior author and the first author. The order of these coauthors can be based on the importance of their contributions to the work in descending order from the first author. Decisions on authorship need to be made before the

paper is written. It may be appropriate to change the order of the authors as the manuscript preparation progresses. The senior author and the first author should take the lead in any decision to revise author order, but such decisions should involve all the coauthors. Sometimes journals require that any change in authorship of a paper under peer review be accompanied by a letter of approval signed by all of the coauthors.

Inappropriate authorship

Certain types of unethical authorship are identified by specific terms that graphically depict the behavior involved. The two most commonly used designations are ghost authorship and guest authorship. Ghost authors, although meeting qualifications for authorship, are those whose names have been deliberately omitted from the byline of the paper. A guest author, on the other hand, is one who does not qualify for authorship but whose name appears in the byline. Both ghost and guest authorships are inappropriate.

Ghost authorship falls into two distinct categories. The first involves someone who has legitimately participated in some aspect of the research but whose name is omitted from the byline and the acknowledgments for various reasons, e.g., their employment by a corporate entity. More commonly, ghost authors are actually ghostwriters, who analyze data, compose data presentations, and write the manuscript. This may be done on a fee-for-service basis, and a corporate sponsor may even finance this arrangement. Why is ghostwriting wrong? Ghostwriters are removed from the accountability that is attached to authorship. Moreover, transparency is further eroded by the inability to critically evaluate possible conflicts and bias that may be associated with the ghostwriter.

A second meaning of the term "ghost authorship" involves authors who participated in the research as collaborators in a way that meets authorship criteria. However, when the paper is published, their names do not appear in the author byline. This may be the result of deliberate inappropriate denial on the part of the other authors or confusion, misunderstanding, or lack of communication between the collaborators. Although this use of the term "ghost authorship" has a different meaning from the first category described above, it is also wrong because it denies authorship to someone who qualifies for and deserves a place in the byline of the paper.

Guest authorship is grounded in the expectation that inclusion of a particular name in the author byline will enhance the paper's chances for favorable peer review and, ultimately, for being published. The guest author's status and visibility are expected to elevate the quality of the paper. But guest authors do not contribute to the paper in ways that justify authorship; thus their name in the byline is inappropriate. A nuanced form of guest authorship is called honorary or gift authorship. In this case, instead

of the author's name being able to enhance the status of the paper, the honorary or gift author is afforded a place in the byline by virtue of his or her position, e.g., a departmental chair or institute director. In fact, this is an inappropriate courtesy that gives the honorary authors credit where none is due.

Acknowledgments

The "Acknowledgments" section of a scientific paper is typically described in guidelines as being reserved for those people whose contributions to the work do not meet the criteria established for authorship. This might include someone who provided needed technical help but did not have a full appreciation of the experimental work. Or it might be someone who provided writing or editorial assistance but participated in no other aspect of the work. The ICMJE takes this a step further and recommends the "Acknowledgments" section as the place to include individuals who have contributed "materially" to the work but whose contributions do not justify authorship, e.g., "scientific advisors" or "clinical investigators." The ICMJE recommends that written permission be obtained from anyone mentioned in this section, as readers are likely to infer their endorsement of the data and conclusions by virtue of their acknowledgment.

Peer Review

Many scientists are called on to review manuscripts. This happens in two ways. First, scientists may be appointed as editors or as members of editorial boards of scientific journals, in which case their duties as reviewers are formalized. Such appointments are made for a defined period of time. Usually editors (or editors-in-chief) oversee the process, distributing manuscripts to board members. Their names appear on the masthead of the journal—in print, online, or both—designating them as reviewing editors, editorial board members, or an equivalent term. Second, scientists may be asked to be *ad hoc* reviewers. In this case, they receive papers to review from editors or editorial board members and are asked to evaluate them as a courtesy. Usually, *ad hoc* reviewers are acknowledged on a regular basis in the journal. Many scientific journals rely heavily on *ad hoc* reviewers. The contribution made by *ad hoc* reviewers is an important part of professional citizenship. For many journals, *ad hoc* reviewers comprise the workforce that enables the process of peer review to function. Although editors—especially those in high-level oversight positions—may be compensated by journal publishers, *ad hoc* reviewers typically receive no remuneration for their work.

All reviewers in general and *ad hoc* reviewers specifically provide a critical service. They prepare written evaluations that help editors decide on

the acceptability of the submitted manuscripts. Equally important, their comments often allow the authors to improve their manuscript if it is not acceptable for publication in its current form. Reviewers may suggest improvements in writing style, presentation of data, or even further experiments to be done.

Journals, professional societies, and related organizations publish guidelines or policies that speak to the process of peer review and the responsibilities and ethical conduct of those involved in the peer review process. A selection of such sources is provided at the end of this chapter. Here we'll use an amalgamation of these and similar resources to describe the flow of a manuscript through a typical cycle of peer review. Then we'll discuss the duties and responsibilities of the peer reviewer and others in the peer review process.

The workings of peer review

Typical peer review begins with submission of a manuscript to an editor or to a central office of the publisher of the journal. In the latter case, office staff assign the manuscript to an editor. Electronic submission of manuscripts is the rule rather than the exception, with the overwhelming majority of scientific journals providing a computer interface to upload the manuscript, supporting materials, and relevant correspondence or submission forms. Usually scientific journals have multiple editors who represent the various subspecialties of the subject matter. The editor then reads the paper to decide whom to ask to review it. Editors may select editorial board members or *ad hoc* reviewers for this job. Typically a single paper is assigned to two or three peer reviewers (also termed referees). Again, this process and all remaining transactions occur electronically, using interactive website interfaces, file transfers, or both. Some journals provide special forms or online data fields on which to prepare manuscript reviews, but these frequently consist of lots of blank space for the reviewers to write comments. There may also be a separate form for comments that are intended only for the eyes of the editor. The editor asks the reviewers to complete their evaluations in a specific period of time, usually 2 weeks to a month. When the completed reviews are returned to the editor, he or she reads them. The editor then makes one of three decisions: (i) accept the paper, (ii) reject the paper, or (iii) return the paper to the authors for revision. In all cases, the editor provides the authors with a communication (e.g., e-mail) indicating the basis of his or her decision. Obviously, in the case of outright acceptance, the text is brief. However, editors are usually specific in their decision letters when explaining rejection or the need for revision. Such letters reflect the editor's own opinions of the paper, along with the reviewers' comments and recommendations. Along with the editor's message to the authors go the verbatim copies of the reviewers' comments. The parts of the review forms that indicate the reviewers' recommendation ("accept," "reject," or "revise") as well as any comments exclusively made to the editor are not sent to the authors. Editors may use comments sent to them separately by reviewers to help in composing their decision letter.

For most scientific journals in the biomedical and natural sciences, the comments of the reviewers are anonymous. However, some journals do reveal the identity of reviewers to the authors. This can be done as a matter of policy or by encouraging reviewers to sign their written reviews.

Authors consider the reviewers' and editor's comments in revising their papers. They may make changes based on comments they agree with. Alternatively, authors have the right to rebut any and all criticisms of the reviewers. The basis for handling each of the reviewers' comments must be explained to the editor in a letter that accompanies the revised manuscript. It is then the editor's job to reach a final decision on the paper and to notify the authors.

Being a peer reviewer

Manuscripts for review usually arrive via e-mail attachment or are downloaded from a secure website of the publisher. Upon receipt, there are a number of housekeeping chores that reviewers must do, and it is important and courteous to attend to these quickly. First, the reviewer must scan the paper and decide whether he or she is qualified to review it. The review deadline must be evaluated: can the reviewer complete the review in the time allotted by the editor? If the reviewer is uncomfortable with either of these criteria, the manuscript should be sent back to be reassigned. Also, reviewers should check that they have a complete version of the manuscript. Are all the pages, figures, tables, and supplemental material, if any, accessible to the reviewer? If anything is missing or in need of attention (e.g., a low-resolution image that cannot be properly evaluated), the editor or editorial office should be contacted to rectify the problem.

Reviewers must be comfortable with the job of impartially reviewing the work. Their review of the paper must not constitute a conflict of interest, real or perceived. Typically conflicts include papers from investigators at the reviewer's institution, trainees who have recently been in the reviewer's lab, or collaborators of the reviewer at the reviewer's own or other institutions. Commercial interests also create conflicts. For example, is the paper authored by scientists at a company that pays the reviewer as a consultant or has made a grant or gift to the reviewer's research program? Conflict-of-interest decisions of this type usually rest with the reviewer. Most of the time, the information that points to the conflict is known only to the reviewer, and the editor may never become aware of it. An extension of such internal conflicts moves into the realm of conflicts of conscience

(see chapter 7). Can a scientist who believes it is inappropriate to use cells derived from human fetal tissues in research objectively review a paper that reports the results of human embryonic stem cell experimentation? The reviewer has to decide whether there is conflict or whether others might perceive specific actions as conflict. A simple rule is "When in doubt, don't review the paper." The reviewer may contact the editor to seek advice on matters of potential conflict. In general, any extensive rationalization for overcoming what might be a perceived conflict is usually a signal to both the reviewer and the editor that a real conflict may exist or may be perceived by others. In such cases, reassignment of the manuscript to another reviewer is necessary.

If a reviewer returns a manuscript for reassignment, it is a courtesy to tell the editor the reason for doing so. It is also customary to suggest the names of potential substitute reviewers. Such help is valuable, and editors appreciate it.

Some of the guidance commonly found in peer reviewer guidelines follows.

Philosophy of review

The peer reviewer's job has two aims: (i) to help the editor make a good decision on the acceptability of the paper and (ii) to help the authors communicate their work accurately and effectively. The peer reviewer does not have to be an adversary to do either of these jobs. Especially in the latter case, the reviewer should be an advocate for the authors. Indeed, guidelines sometimes urge reviewers to take a positive attitude toward the manuscript. Frequently, peer reviewer guidelines caution against the use of derogatory or libelous comments and *ad hominem* remarks. Reviews that are confrontational are distressing to authors and often make things difficult for all involved. Meaning sometimes gets lost in impolite and ill-considered language, and this can make the editor's job of evaluating the reviewer's comments confusing. It can distract and mislead authors as they prepare their rebuttals. Authors may "miss the point" and in doing so fail to improve their manuscript. Additionally, time is often wasted when authors feel the need to respond in kind to offensive language in their rebuttal letters to editors.

Confidentiality

A manuscript sent to a reviewer is a privileged communication. It is confidential information and should not be shared with colleagues except under prescribed conditions. For example, if it is necessary for the reviewer to get assistance from colleagues in performing the review, guidelines usually allow this only if permission from the editor is sought and received. Such guidance is often explicitly stated in peer review policies provided by

journal publishers. Generally, the same holds true with regard to sharing manuscripts with trainees. The opportunity to have a predoctoral or postdoctoral trainee critically evaluate an unpublished manuscript may provide a valuable learning experience. However, permission to allow a trainee to do this should always be sought and received from the journal editor. Peer review instructions published by some journals specifically address this, acknowledging the value of the experience for the trainee but cautioning that assigned reviewers should not share manuscripts with trainees without editorial permission. At least one scholarly organization, the Society for Neuroscience, makes an exception for trainees, stating in its Guidelines for Responsible Conduct Regarding Scientific Communication that

> A reviewer may bring an immediate lab member with appropriate expertise into the process for training purposes. In such situations, the reviewer is responsible for ensuring that the trainee fulfills all obligations for confidentiality, and the reviewer must report to the journal the identity of the trainee. The reviewer remains fully responsible for the content and quality of the review.

A customary policy is that a peer reviewer should never contact an author directly about the manuscript under review. This sounds like unnecessary advice because most journals use anonymous review. However, even if journals allow disclosure of the reviewer's identity to the authors, direct contact between the two during the review process is usually forbidden. The reviewer's opinion about the merit and acceptability of a manuscript is considered by the editor, who makes the final decision. By talking to authors, reviewers may communicate misleading messages that can make the editor's job more difficult. Thus, reviewers who need clarification or additional information should contact the editor and let him or her obtain it from the author.

Common criteria for evaluating merit

The manuscript should contain a clear statement of the problem being studied, and it should be put in perspective. Reviewers should evaluate this perspective in the context of appropriate literature citations. In other words, are the authors giving appropriate credit to prior work in the field, especially those contributions upon which the present report is built? The originality of the work should be carefully weighed. The reviewer should consider whether the manuscript reports a new discovery or if it extends or confirms previous work.

Experimental techniques and research design should be appropriate to the study. Did the authors use the right tools and techniques to test their hypotheses? Description of methods is very important. This is the part of scientific communication that permits verification of the work. The description of the materials and methods should provide enough detail so

that other investigators can repeat the work. It is acceptable for some methods to be mentioned briefly and then cited in the references. However, such citations should be the correct ones. Papers should not be used as methods citations if they contain incomplete descriptions or if they refer to an intermediary paper for the details of the method.

The reviewer should examine the presentation of data for clarity and effectiveness, keeping in mind several questions. Is data presentation cluttered or confusing? Are figures and photographs unclear? What about the organization of the data seen in tables and figures? Are there too many tables or figures? Can some be deleted? Would data given in tabular form be better presented in figures? Should data in tables be combined or single-panel figures redone as multipanel ones?

Interpretations of the data need to be sound and clearly worded. The discussion of the work should be appropriate: arguments should be logically presented, and any speculation should be built on data in the paper or the existing literature.

The writing in the manuscript should be clear, easy to follow, and grammatically correct. Many guidelines affirm that the peer reviewer's job is not to rewrite the manuscript. However, citing examples of writing deficiencies will help the authors in making global revisions. The reviewer should also note whether the authors are adhering to correct scientific nomenclature and abbreviations as specified by the journal.

The reviewer should evaluate the title and abstract after reading the paper. Are they adequate and appropriate? With the widespread adoption of electronic publication, the abstract has become the first line of scientific communication. Thus, the abstract needs to clearly describe the essence of the problem, how it was approached, and the outcome of the research.

Writing the review

The format for preparing a manuscript review varies from journal to journal. In some cases, there is a template of topics of questions about the manuscript that must be addressed by the reviewer. In many cases, the review instructions provide some guidance and then leave it to the reviewer to present his or her review in narrative form. In such cases, it is typical for a review to begin with a paragraph or two that summarize the major findings and highlights of the paper. If there are overriding considerations, either positive or negative, they are presented here. Shortcomings or flaws that have influenced the reviewer's assessment of the paper should be stated in general terms.

Following this narrative, it is customary for the reviewer to list specific, numbered comments. Numbering makes it easier for the authors to respond to the critique and for the editor to make a final decision. Specific comments should offer guidance to the authors on how to improve their work. Problems should be identified and solutions suggested where possible.

Finally, it is customary for the reviewer not to indicate in the narrative or in the specific comments the ultimate recommendation for the paper. Instead, this should be clearly transmitted to the editor. As mentioned earlier, it is commonly done with a specific form or in a brief note. There is a reason for this. Rarely do editors send a paper to just one reviewer; using two or three experts is the norm. Reviewers can and do disagree about the merits of the same paper. When this occurs, it is the editor's job to sort out the reviews and then write his or her final disposition in a decision letter to the author. It is frustrating to the authors to read two reviews of the same work, one explicitly recommending acceptance and the other explicitly recommending rejection.

Debating peer review

The peer review process seems to be under regular scrutiny and debate. Like most things driven by human judgment and behavior, it is often cited as being imperfect. The fundamental nature of the process is a case in point. Most journals still use the single-blind system. That is, the identity of the reviewers remains anonymous throughout the process. Double-blind systems, where the identity of the authors and the reviewers are blinded to all but the editors, have been tried and are occasionally used. The principal argument for this system is to reduce bias, but double-blind peer review is often criticized on the grounds that it is difficult, if not impossible, to render a manuscript free of all information that would suggest or identify the author or authors.

Inherent bias in peer review is sometimes offered as a weakness that may limit the integrity and effectiveness of the process. Earlier in this chapter we discussed examples of conflict of interest that could form the basis for not accepting the assignment to review a manuscript. For example, conflicts are created when the authors are collaborators or recent trainees of the reviewer. But consider the case where an expert peer is asked to review a paper reporting results that are in an area that is close to or overlaps with her own research. The culture of confidentiality embraced by the peer review system notwithstanding, this situation is rife with temptation for the reviewer. There may be new information in the paper that would benefit the reviewer, but it clearly should not be put to such use. Contrast this with a timely review of the paper that recommends acceptance of the manuscript and, in doing so, precludes the reviewer from publishing and getting the credit for and recognition of priority of her work. Another possible scenario—one that invokes harmful intent—involves the reviewer delaying the review of the paper or delivering an unjustified harsh review in order to gain an advantage in getting his work published in

advance of the competing paper. Thus, the need for expert review to assure the quality of published research findings is sometimes pitted against the conflicts that may compromise its integrity. In this particular case, the reviewer is best advised not to accept the assignment to review the manuscript.

Finally, let's consider whether peer review is able to detect fraudulent data, i.e., fabrication and falsification. This question is subject to ongoing discussion in both scientific and public communities. Journal commentaries and opinion pieces written by scientists and publishers focus on the "limits of peer review" and whether "peer review can police fraud." The upshot of the discussion by scientists and publishers is that the process of peer review generally is not designed to detect fabricated and falsified results. Certainly, as discussed above, the use of text-similarity detection software can detect plagiarism, and the use of such programs is emerging in the peer review process. The same argument can be made for the increasingly used forensic methods for detecting inappropriately manipulated digital images. These methods are capable of preemptively detecting doctored images. However, it should be noted that even with this process in place at one journal, a high-profile case emanated from the report of a whistle-blower and not as the result of electronic monitoring of a photograph for manipulation that resulted in deception.

The focus of the public media is more subjective and typically embraces the expectation that peer review is able to detect fraud. For example, newsprint articles on publications that contain fabricated and falsified data have invoked the "failure of the vaunted peer review" system as a contributing cause in the publication of fraudulent results. Similarly, statements in articles on research misconduct claim that the peer review system in science is designed to "root out" research fraud. Both of these assertions are misguided.

So what are the realistic expectations of the peer review process when it comes to papers that contain fabricated or falsified data? Media writers do not offer the details of why the peer review process should be able to detect bogus data in the first place. Instead, peer review of scientific publication is usually blamed in whole or in part when fraudulent published data are uncovered. The reasons for the "failure" are not totally developed but often include accusations of failure to uphold review standards or shortcuts taken to publish high-impact research papers. The arguments from the publishing and scientific communities are drawn from the day-to-day involvement in the process and observations of its operation. Generally, these arguments hold that detecting fabricated or falsified data that have been created to deliberately deceive the peer reviewer and, ultimately, the reader is practically impossible. Usually, perpetrators of fraudulent data are careful enough in their fabrications and falsifications to generate data

sets that don't raise suspicions or seem "too good to be true." So recognition of such data as fraudulent at face value is not possible. Moreover, editors and peer reviewers typically do not receive original data outputs, records, and related materials as part of the review process. This makes detection of deliberately crafted fraudulent research data even less likely during the review process.

In general, peer reviewers assume that research findings in manuscripts are reported honestly and without intention to deceive the reader. The whole process is built around trust in the authors' conduct and reporting of the research. The process expects that peer reviewers will judge the appropriateness of methods selected to address the problem, the nature and appropriateness of the data analysis, the plausibility of the interpretation of the data, and whether the conclusions of the paper are consistent with the data analysis and interpretation. In the absence of whistle-blowing or of electronic detection of plagiarized material or manipulated digital images, it is reasonable to posit that the best tool for detecting fraudulent research results is what many call the "self-correcting" nature of science. Namely, over time results that have been fabricated or falsified will not withstand the scrutiny of additional research designed to repeat or build on them.

Publication's Changing Landscape

Open Access

Digital technology began to have a significant impact on the publication of scientific literature in the early 1990s. As mentioned above, the transactions of peer review now are typically conducted electronically. Moreover, the logistics of producing the final article have become electronic and online journals now regularly accompany the print versions. The costs for receiving the print journal and having access to the electronic version of the journal are largely borne by subscribers, with the authors usually paying some of the costs of publication. A number of publishers make electronic versions of their journals available for public access from their websites without charge after a defined period of time (e.g., a year). A related practice of many publishers is to also allow papers supported by various research funders (e.g., the NIH) to be placed in public repositories and made available at no charge within months following the original publication date. One such repository, PubMed Central, will be discussed below. Publishers of some subscription journals that produce both print and online versions offer a payment option that creates immediate, free access to online publications. Specifically, the author is given the opportunity to pay a fee in addition to standard publication charges. In return for the fee, the publisher makes the online file of the author's paper available to readers at no cost as soon as it is posted to the journal's website. Thus, authors

electing to pay the fee have their publications placed in the public domain immediately.

A second model for publishing research papers, Open Access (OA), also began in the 1990s. In this model, papers are published electronically without a corresponding print version. Instead of a subscription fee paid by readers, the publication costs in the OA model are borne totally by the author. Thus, OA publication is often referred to as an "author pays" model. Peter Suber has written extensively about OA publication and defines it simply: "open-access literature is digital, online, free of charge, and free of most copyright and licensing restrictions." Copyright, as mentioned earlier and discussed in chapter 9, is that form of intellectual property law that protects the expression of a tangible work product. Copyrightable works include such things as writings, images and audiovisual products, sound recordings, sculptures, choreographic works, and computer source code. Copyrights protect the expression of ideas but not the ideas themselves. For example, the words in a journal article are protected by copyright exactly as they appear on the page. However, the ideas they contain or may convey are not protected by copyright. As intellectual property, copyrights are owned by their creators, but they may be licensed, sold, or allowed to be used with permission of the creator.

Meetings of interested parties held in Budapest, Hungary (2002); Bethesda, MD (2003); and Berlin, Germany (2003) gave rise to position papers that defined OA, made recommendations about its development and use, and provided a platform for its engagement and endorsement. The Bethesda Statement on Open Access Publishing defines OA publication as follows.

> An Open Access Publication is one that meets the following two conditions:
>
> 1. The author(s) and copyright holder(s) grant(s) to all users a free, irrevocable, worldwide, perpetual right of access to, and a license to copy, use, distribute, transmit and display the work publicly and to make and distribute derivative works, in any digital medium for any responsible purpose, subject to proper attribution of authorship, as well as the right to make small numbers of printed copies for their personal use.
> 2. A complete version of the work and all supplemental materials, including a copy of the permission as stated above, in a suitable standard electronic format is deposited immediately upon initial publication in at least one online repository that is supported by an academic institution, scholarly society, government agency, or other well-established organization that seeks to enable open access, unrestricted distribution, interoperability, and long-term archiving (for the biomedical sciences, PubMed Central is such a repository).

Condition 1 of the Bethesda Statement is referred to as Gold OA and is represented by OA journals that conduct peer review. Condition 2 is termed Green OA and refers to literature that has already been peer reviewed and has been deposited in repositories (e.g., PubMed Central) where it is available to all users without charge.

An inventory of OA journals is maintained online at the Directory of Open Access Journals. According to this site, the census of OA journals in mid-2013 was approximately 9,600. By the end of the first decade of the millennium, the OA journal count was increasing by more than 1,000 journals per year. The growth and impact of OA journals has been the subject of various studies. In a 2011 study, significant findings included dramatic growth of OA journals over a 15-year period compared with the number of new subscription journals: 15 versus 3% per year. Data suggest that awareness of the existence of OA journals has grown within the scientific community, as has the use of OA journals for publishing research results. OA journals have the ability to publish large numbers of papers per year compared with non-OA journals. Such numbers for some OA journals can easily exceed 1,000, and in 2012 one OA journal published more than 23,000 articles. Subscription journals publish a range of articles per year from several dozen to upwards of 1,000 or even higher. Attitudes favoring OA publishing included free accessibility to readers along with the desire to reach a wide readership.

Repositories

The repositories mentioned in the previous section are digital archives into which journal articles are deposited, thus placing the paper into the public domain. Most notable in this regard is PubMed Central, a repository operated by the U.S. National Library of Medicine. In 2008, the NIH began requiring that all publications reporting research supported by an NIH grant must be deposited in electronic format on the PubMed Central site within 12 months of the publication date. This requirement is in the process of being expanded. In early 2013, the Office of Science and Technology Policy (an office of the executive branch of the U.S. government) requested that all U.S. federal agencies "with over $100 million in annual conduct of research and development expenditures" create plans to increase public access to federally funded research results. There are approximately 20 federal agencies that would fall into this category. Public access to peer-reviewed publications must be addressed such that the public "can read, download, and analyze in digital form final peer reviewed manuscripts or final published documents." The plan must use a 12-month postpublication embargo, similar to the NIH requirement, as a guideline for making papers publicly available.

This Green OA policy is also employed by funding agencies outside of the United States. Research Councils UK, the partnership of the seven Research Councils of the United Kingdom, now requires that papers reporting research results obtained under grants from the Research Councils

be made free to public access within 6 months of the publication date of the paper. Repositories for depositing papers—selected at the authors' discretion—include PubMed Central, Europe PubMed Central, and the Economic and Social Research Council Research Catalog. Private research funding agencies such as the Wellcome Trust (London, United Kingdom) and the Howard Hughes Medical Institute (Chevy Chase, MD) have similar policies in place. There is strong sentiment by funding agencies worldwide that scientific publications resulting from agency support should be OA, and this is likely to result in increases in the use of Green OA. The Action Plan towards Open Access to Publications published in 2013 by the Global Research Council affirms this notion.

Preprint servers

In 1991, physicist Paul Ginsparg created a server-based archive for authors to upload unreviewed manuscripts that would then be freely available in the public domain. Ginsparg's original vision in this venture was to provide an electronic bulletin board intended to serve his colleagues working in the field of theoretical high-energy physics. Preprints in this discipline had historically been exchanged by postal mail service, and his rationale was to "level the research playing field." That is, his repository would replace this limited distribution of photocopied manuscripts among selected colleagues with a globally accessible electronic repository that would serve all levels of the scientific community from students to senior scientists. He called his repository arXiv (pronounced "archive," with the X representing the Greek letter chi), and within 2 years it had achieved traction as a global resource for researchers. Among other things, it "became a place to stake intellectual precedence claims, catalyzing further growth," according to Ginsparg. Some 20 years after its launch, arXiv is now hosted and operated by Cornell University (Cornell University Library), where Ginsparg is a faculty member. Preprints (called e-prints on the site) hosted on arXiv exceeded 850,000 in mid-2013 and included manuscripts in the disciplines of physics, mathematics, computer science, quantitative biology, quantitative finance, and statistics.

Ginsparg's creation of arXiv launched a concept that has been replicated extensively since 1991. Today, preprint servers are hosted by scientific societies and other organizations, publishers, universities, specialty groups, and even individuals. Some are underwritten by government sponsors. Preprint servers tend to be discipline specific to a greater or lesser degree. All embrace the objectives of rapid information dissemination and the free and open exchange of scientific information. Although some preprint servers reserve the right to reject submissions or to change the topic classification suggested by the authors, arguments based on the lack of peer review have been made against the concept. Criticisms have centered

on the reliability of the material being posted. Specific criticisms range from lack of quality control with respect to the depth of experimental details to improper or omitted citations. Because preprint servers usually allow for revisions or updates of posted material, some argue that this creates an opportunity for abuse. Posting of material on preprint servers typically is in perpetuity, and some have objected to this.

Scientists posting their unreviewed manuscripts on preprint servers should be aware of consequences that may come from their choice to do so. First, a preprint may accidentally or unknowingly contain proprietary information. Disclosing such information in the public domain may preclude the ability to gain intellectual property protection of it (e.g., a patent). If there was any reason to believe the manuscript contained proprietary information, then the author would be well advised to file for a provisional patent (see chapter 9) before posting it to a preprint server. Copyright ownership may be an issue depending on the preprint server being used. For some preprint servers, posted papers are in the public domain and the host's position on copyright is silent. Other preprint servers hold the copyright by virtue of the author providing a nonexclusive license. Yet others afford arrangements to create public copyright licenses under the nonprofit organization Creative Commons. Last, and arguably most important, is that most publishers of peer-reviewed journals require that authors may not submit manuscripts that contain previously published material. Some peer-reviewed journals consider material that has been placed on a preprint server to be an electronic publication, and as such, this action forfeits the authors' rights to submit any or all of it for consideration. This is illustrated in the policy of the journals of the American Chemical Society.

> A preprint will be considered as an electronic publication and, according to positions taken by most Editors of ACS journals, will not be considered for publication. If a submitted paper is later found to have been posted on a preprint server, it will be withdrawn from consideration by the journal.

Other journals make accommodations for manuscripts that have been posted to preprint servers, as illustrated in *Nature*'s current policy.

> Our policy on the posting of particular versions of the manuscript is as follows:
>
> 1. You are welcome to post pre-submission versions or the original submitted version of the manuscript on a personal blog, a collaborative wiki or a preprint server at any time (but not subsequent pre-accept versions that evolve due to the editorial process).
> 2. The accepted version of the manuscript, following the review process, may only be posted 6 months after the paper is published in a *Nature* journal. A publication reference and URL to the published version on the journal website must be provided on the first page of the postprint.

3. The published version—copyedited and in *Nature* journal format—may not be posted on any website or preprint server.

For open access content published under a Creative Commons license, authors can replace the submitted version with the final published version at publication as long as a publication reference and URL to the published version on the journal website are provided.

Clearly, the use of preprint servers has provided a novel dimension to the concept of OA. They have gained acceptance and provide a useful source of information to researchers across many disciplines. But the decision to upload an unpublished manuscript on a preprint server requires forethought and planning so that doing so does not confound or preclude the possibility of subsequent peer-reviewed publication or of protection of proprietary information.

Postpublication review

In the early 2000s, a corporate endeavor was launched that allowed postpublication peer review online. Originally called *F1000—Faculty of 1000 Post-Publication Peer Review*, it was composed initially of 1,000 selected scientists who posted on the *F1000* site their comments on peer-reviewed publications in biomedical fields. In a little more than a decade, this enterprise has evolved into three separate services. F1000Prime is now a postpublication service that publishes "Article Recommendations" made by the F1000 Faculty. F1000Research is an OA journal covering the life sciences. Articles are published immediately after a preliminary review and are subject to peer review once posted on the F1000Research site. The names of the peer reviewers and their comments are published online with the article. F1000Posters is an OA repository for poster and slide presentations. F1000Prime now consists of 5,000 scientists and clinical researchers, assisted by another 5,000 associate faculty members. F1000 reviewers use a rating system of three levels: good, very good, and exceptional. Reviewed articles are catalogued and are searchable on the F1000Prime site. Users of the F1000Prime service pay a fee. Subscribers to F1000Prime may post comments on the Article Recommendations made by Faculty. However, subscriber comments that are considered "defamatory or otherwise abusive" can be reported and may be removed by F1000Prime.

Organizations, groups, and individuals also are contributing to the growth of postpublication peer review using freestanding blogs, social media, and other online mechanisms. However, with these media, the commentary does not always meet the etiquette prescribed by the policy mentioned above, and individually sponsored blogs and social media typically do not have policies that deal with inappropriate remarks or mechanisms in place for removing them. Not unexpectedly, such comments occasionally appear. Arguably, the emergence of cultural norms that would suppress if not eliminate such behavior can be expected over time.

Another area that has been the subject of discussion involves what, if any, obligation authors have to respond to comments. This applies to all forms of postpublication review, but especially to comments appearing on independent blog sites or in the various forms of social media. To be sure, there have been multiple examples of online criticisms that have faulted methodology, interpretations, and conclusions. In the absence of relevant cultural norms, authors' comments have varied significantly. In one case, the authors acknowledged a technical error, leading to a published "expression of editorial concern" by the journal's editor. In contrast is another well-known paper that claimed the discovery of a microorganism that was able to replace the use of phosphorus with arsenic, an assertion that would have a profound impact on the composition of DNA. Despite an intense attack on the paper's methodology, results, and conclusions, the authors refused to engage their online critics, arguing that such comments should be moderated in the peer-reviewed literature. The upshot was a series of technical notes and published and unpublished papers that to date present a compelling case against the findings and conclusions of the original paper.

There is much left to play out on the field of postpublication review. Despite some high-profile cases involving strong critiques and their sequelae, online commenting is far from commonplace. The critical nature of some comments and the speed at which they appear postpublication may be daunting to some authors in the absence of protocol that would guide a response. In an article titled "Response Required," the Nature Publishing Group has taken the editorial position encouraging "postpublication discussion on blogs and online commenting facilities as a complement to—but not a substitute for—conventional peer review." In their article "The Paper Is Not Sacred," Adam Marcus and Ivan Oransky argue that the postpublication review process "boosts the long term credibility of the scientific record." They submit that the tangible record of online comments and blog posts will accomplish this. What the postpublication review process evolves into will ultimately depend on the engagement of the relevant stakeholders along with a critical analysis that seeks to reveal its true value to the scientific record.

Publication metrics

The advent and proliferation of digital journals has accelerated and amplified the use of metrics associated with scientific papers. The most established and influential of these is the journal impact factor (IF). The impact factor was conceived and developed several decades ago by Eugene Garfield, who initially published it under the banner of the Institute for

Scientific Information. Today, the Institute is known as Thomson Reuters, and journal IFs are published annually on Thomson Reuters Web of Science, a repository for databases dealing with research data, research publications, and patents. The IF calculation is meant to express a journal's average citation frequency. The underlying assumption is that the more that papers published in a journal are cited in other publications, the higher the quality of the journal. The use of the IF metric has given rise to the commonly used phrase "high-impact journal." The IF is expressed as an annual metric but is based on the average number of citations received per paper appearing in the journal over the previous 2 years. For example, consider a journal with an IF of 4 as published in the Thomson Reuters Journal Citation Reports 2012 Release. This would mean that the total of all citations in 2012 made to papers published in the journal during 2010 and 2011 divided by the total number of journal papers during this biennium would equal 4. Only citations in journals that are indexed by the Journal Citation Reports are used in the IF calculation.

The use of the IF has been criticized because it is frequently misused as an indicator to judge the quality of work of individual scientists and institutions. In fact, the IF metric was originally devised to help librarians make subscription decisions based on journal quality. Some argue that using the IF as a research quality proxy for individual scientists leads to the questionable conclusion that it's not what you publish but where you publish. Further arguments focus on the ill-advised selection of journals for publication based on their IF instead of factors like the appropriateness of the journal's readership and the expertise of the editor and editorial board.

The American Society for Cell Biology convened a group of scientists, journal editors, publishers, scholarly societies, and funding agencies at its annual meeting in 2012 to discuss journal IFs and their use. The outcome of this meeting was the San Francisco Declaration on Research Assessment released in mid-2013. The Declaration is subtitled "Putting Science into the Assessment of Research," and its 18 recommendations aim to "improve the ways in which the output of scientific research is evaluated by funding agencies, academic institutions, and other parties." The first recommendation is overarching and calls for the elimination of journal IFs and related metrics in the assessment of an "individual scientist's contributions, or in hiring, promotion, or in funding decisions." The Declaration has more than 200 signatories, including individual scientists, editors, publishers, scientific societies, and funding agencies. However, there were a number of high-profile publishers and groups that did not sign the Declaration. The Declaration also was endorsed in journal editorials published to coincide with its release. The recommendations provide a framework that promotes new attitudes toward journal publication metrics, provides new prescriptions for their use, and even suggests changes in publication practices that would have an impact on how scientific research is reported. Acceptance of the Declaration's recommendations will have to involve a variety of participants including researchers, publishers, institutions, funding agencies, and organizations that collect and provide metrics. This will add complexity and time to whatever implementation will be achieved.

Unlike the IF, which was intended to measure journal quality, there is another metric designed to measure the impact of a researcher's publications. Developed by Jorge Hirsch, the h-index calculation—like the IF—is based on citation frequency. The h-index measures both productivity and impact. The h-index calculation begins with a researcher's body of publications. Hirsch defines the h-index as "the number of papers with a citation number higher or equal to h." Thus, if at the time of calculation a researcher has published 130 papers and 33 of those papers have been cited 33 or more times, then the h-index is 33. Since its inception in 2005, there have been a number of variants of the h-index proposed, including ones that give more weight to highly cited articles (Egghe's g-index) or to more recently published articles (contemporary h-index). Some researchers present statistics, including their h-index, in the publication sections of their *curricula vitae*. Other investigator statistics that sometimes get added to *curricula vitae* include graphic representation of the researcher's papers published over time and citations of all of his or her papers on an annual basis. Graphics for these can be easily prepared using the Thomson Reuters Web of Science site.

It should be noted that some journals (both OA and subscription) now include metrics associated with the online version of each paper they publish. Data that can be accessed at these sites include the number of citations in various databases, page views and downloads, mention in social media, and coverage by the news media.

A final metric bears some discussion, namely the frequency at which published manuscripts are retracted. Papers may be retracted in whole or in part voluntarily by authors for reasons of errors in logic, errors in methodology, irreproducibility, or other honest mistakes. Papers also may be retracted by authors or by publishers as the result of confirmed or suspected research misconduct: fabrication, falsification, or plagiarism. When a paper is retracted, the citation and the online article (on PubMed Central and the online journal) will indicate this status, meaning it should not be considered valid. A partial retraction indicating that some but not all data are invalid may be in order and used in lieu of a full retraction. Studies show that the number of retracted articles in biomedical journals has risen significantly since the beginning of the millennium. Using the PubMed database, one study reported that total retractions (as indicated by a retraction alert associated with the citation) rose from 28 in 2001 to 407 in 2011. However, estimates are that PubMed now adds a half-million new

citations per year, making even the most recent number of retracted papers a very small fraction of papers in the database.

In another study, Ferric C. Fang, R. Grant Steen, and Arturo Casadevall reviewed approximately 2,000 biomedical and life sciences papers that had been retracted as identified in the PubMed database. This resource references more than 25 million biomedical research articles published since the 1940s. Two important points were reported by these authors. First, the earliest retraction of an article they found was in 1977 (originally published in 1973). This suggests that retraction of publications in the biomedical literature is a relatively recent development. Second, and more importantly, their analysis found that that 67% of the retractions were connected to some form of research misconduct.

Unfortunately, retracted papers may still be incorrectly cited (i.e., cited without acknowledging that they have been retracted). This could be the result of oversight or could conceivably be the result of deliberate deception. Alternatively, confusion caused by retracted papers available on nonpublisher websites—but not noted as being retracted—may contribute to incorrect or inappropriate citation.

Conclusion

Written communication is an essential part of scientific research. Science benefits society only insofar as its findings are made public and applied. Indeed, biomedical scientists have a moral obligation to share new knowledge in order to advance and improve the health and well-being of humankind. Scientific knowledge is accepted only when the published research results that support it hold up under scrutiny and independent corroboration.

In the past, many of the decisions about authorship on scientific papers were based on unwritten norms and standards. In recent years, written guidelines for authorship have been promulgated by institutions, societies, and publishers. These provide guidance to authors and can be especially informative to the novice writer.

Providing peer review of scientific publications is an obligation that is shared by scientists. While peer review must be scholarly and rigorous, it must also be timely, respectful, and courteous. Above all, peer review must be constructive. Peer review plays a vital role in the publication of research findings, although the process is being increasingly challenged. Its workings and effectiveness are likely to be the subjects of continuing debate among scientists for years to come. Nonetheless, the process of peer review is performed under both written and unwritten guidelines. Explicit descriptions of the duties and responsibilities of peer reviewers are now frequently published by scientific journals. They aim to foster consistency and integrity in the process.

Since the early 1990s, the scientific literature has been increasingly affected by computers and electronic publication. The peer review process is dependent on electronic communication, as is the actual production of the journal. Access to electronic versions of the published literature has created an effective platform for communicating research findings, and the concept of OA publication offers a new paradigm for both authors and readers.

Discussion Questions

1. Should all coauthors share equally in the blame and punishment when fabrication, falsification, or plagiarism is proved to have occurred in a published paper?
2. What sanctions or punishment is appropriate for those who perpetrate fabrication, falsification, or plagiarism in scientific publications?
3. Should the scientific publication enterprise do more to be able to detect falsified or fabricated data during the peer review process? Why or why not?
4. The editors of *Nature* have taken the position in which they encourage "post-publication discussion on blogs and online commenting facilities as a complement to—but not a substitute for—conventional peer review." (See the "Response Required" citation in the "Resources" section below). Critically comment on *Nature*'s position and provide your reasoning for supporting or rejecting it.

Case Studies

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

4.2 Dr. Ethyl Metzger has published five multiauthored papers during her postdoctoral training. Ethyl shared first authorship on two of these papers. The names of Ethyl and her co-first author were decided by a coin toss as indicated in a footnote according to journal policy. In both cases, Ethyl lost the coin toss and her name appears as the second author in the byline. Her remaining three publications each have five authors in their bylines, and Ethyl is third author on two and fourth author on one. Ethyl is submitting application materials to several institutions to be considered for faculty positions. On her *curriculum vitae* she has changed the order of the authors on her two shared first authorship papers so that her name appears first instead of second. She is concerned that search committees reviewing applications may miss any notation indicating shared first authorship, so she believes the most direct way to assert this is to have her name first in the citation. Ethyl worries that if she doesn't do this there is a risk of her postdoctoral publication record appearing as though she did not publish a single senior-authored paper. She mentions this to you over lunch and asks if you have any concerns about her strategy. What do you tell her? If you have concerns, what guidance or advice do you have for her?

4.3 Aarti Shankar, a new M.D.-Ph.D. graduate, has a hypothesis about a mechanism that would explain an unexpected phenotype displayed by a knockout mouse constructed by her doctoral mentor, Dr. Gina Costello. With Dr. Costello's permission and resources, Aarti experimentally tests her hypothesis in the few remaining weeks before she leaves the lab. Her results reproducibly demonstrate that the mouse is totally missing a minor signaling protein called Xgro. This defect provides a compelling explanation for the knockout phenotype. Aarti leaves for her residency training buoyed by the hope of being an author on a major paper. In follow-up work on the project, Raymond, another postdoc in the lab, is unable to repeat Aarti's work. To Dr. Costello's chagrin, not only are Aarti's data irreproducible but Raymond demonstrates that, to the contrary, the mutant mouse produces 10-fold more Xgro than the wild-type mouse. It takes another 4 months of experiments to rigorously collect confirmatory data. In the process, Raymond also discovers that Aarti's data were the result of her failure to properly conduct the signaling protein assay. Interestingly, Raymond's newly observed overproduction of Xgro provides an attractive alternative explanation for the mutant phenotype. Upon completing the lab work and data analysis, Dr. Costello and Raymond write a manuscript describing their findings on the mechanism underlying the mouse phenotype. Aarti becomes aware of this and requests that she be a coauthor on the paper because her seminal idea was key to the work even though she did the assay incorrectly. Raymond is opposed to this, saying

that Aarti's lab work has delayed submission of this important discovery for publication. Dr. Costello seeks your advice on whether Aarti has a case for authorship. What do you tell her? Why?

4.4 Bella Nassar is a tenure-track assistant professor of psychology who has made good progress in building her professional portfolio in anticipation of achieving promotion to associate professor with tenure. With just a couple of years until she will be eligible to be considered, she is concerned that she is weak in the area of external professional involvement. The school guidelines expect involvement in external activities like service as a peer reviewer, editorial board work, service on external expert panels, and the like. Bella has recently received an unsolicited invitation to serve a 5-year term on the peer review board of an online open-access journal in psychology. Following the invitation, she gets a call from a high-level manager at the publisher's office. The manager urges her to accept the offer. He tells her that as a member of the board she will be expected to submit at least three of her own papers to the journal over the course of her term. To the extent possible, she is told that these papers should cite relevant publications that have appeared in the journal. The publisher tells her that these practices are "good for her and good for the journal." After the call, she has a phone conversation with a current member of the journal's peer review board. He tells her that he has welcomed the opportunity to submit his papers to the journal but has been pressured by the editor-in-chief to cite previous papers published in the journal. He describes the pressure—which he calls "coercive citation"—as a totally transparent effort to increase the journal's impact factor. Bella mulls this opportunity over and is inclined to accept, thus strengthening her case for promotion and tenure. She doesn't think there will be any harm or downside associated with this assignment, even though the practices of the journal strike her as unusual. She comes to you seeking guidance. What's your advice for her, and what's your ultimate take on whether she should accept the invitation to serve on the journal's peer review board? Why?

4.5 Demitri is a senior-level predoctoral student in the department of biological chemistry. A member of his graduate advisory committee, Dr. Chris Sullivan, requires an additional experiment to be completed before Demitri writes his dissertation. Demitri complies with this request, but the results of the experiment itself do not yield any new or useful information. However, a positive control that Demitri conceived and decided to include in the experiment lead him to some surprising results. Ultimately, these findings enable him to prove that a small-molecule ligand in an important receptor binding event is not the native molecule but

a significantly modified metabolite of it. This is a high-impact discovery, and Demitri and his mentor write a manuscript about it. At his predefense graduate advisory committee meeting, Demitri shares the manuscript describing this provocative finding and indicates that it is under review by a prestigious journal. Later that day, Dr. Sullivan e-mails Demitri and his mentor. In strong terms he expresses his dissatisfaction with not being included as an author on the manuscript. His argument is straightforward: if he had not required the experiment to be done, this discovery would never have been made by Demitri. He argues that his insistence on Demitri doing the experiment qualifies as a "significant idea" and that this phrase is commonly mentioned in publication guidelines as a clear rationale for authorship. He goes on to bitterly complain that the manuscript "adds insult to injury" by not even including his name in the "Acknowledgments" section. Demitri is intimidated by the e-mail and argues to his mentor that Sullivan has made a compelling point and that they should add his name to the author's byline, telling the journal it was originally left off in error. As Demitri's mentor, what is your response to that suggestion? What is your analysis of the situation, and what actions will you take as mentor to address Dr. Sullivan's challenge? Why?

4.6 Roger Tibault, a predoctoral student, is first author on a paper just published online in a prestigious journal. Sharing the author's byline is Professor Wanda Whittaker, Roger's mentor, and a postdoctoral trainee. Roger receives an e-mail from a colleague who informs him that the paper is being discussed on a blog. Roger immediately looks at the blog comments. To his chagrin, the anonymous comments are attacking the paper with allegations that a photographic image of a gel blot has been manipulated to deliberately mislead the reader. One blog post displays the results of forensic analyses of the image. The bloggers declare that their results demonstrate that some of the lanes in the gel contain areas that have been "erased" and that there is at least one example of a gel signal that has been "cut-and-pasted" into the image. The experiments that resulted in this gel blot were the team effort of Roger and the postdoc. Roger immediately brings the blog allegations to Dr. Whittaker's attention. He and the postdoc review the data and the preparation of the image with her. They readily admit that the gel blot image was edited to improve its clarity but say that nothing they did was meant to be deceptive, nor did it change the data in the image. Dr. Whittaker is convinced by their arguments. The three then discuss what, if anything, they should do. Should they post a response on the blog defending their position? Should the editor of the journal be notified of the blog posts and the Whittaker group's conclusions? They also consider doing nothing, since some have argued that authors are not obligated to respond to the public comments of individuals outside of the peer review process. Dr. Whittaker even suggests that they consider turning over all of the relevant materials, including the raw data, to the institutional research integrity officer. This could trigger an inquiry into the matter, but Whittaker feels there has been no wrongdoing. So even if disclosure of the situation to the research integrity officer results in an inquiry, she and her colleagues would be exonerated. Do any of these possible strategies have merit? Why or why not? What advice do you have for Dr. Whittaker?

4.7 Fred Taylor—a professor at Western State University (WSU)—collected data on forest conditions and dynamics over a three-state area in the western United States. The project required in-the-field data gathering as well as telemetric data recording. All of the data were gathered and used to create a large computer database under a contract funded by the three states to WSU. Dr. Taylor was the principal investigator of the project, and he and his trainees and technicians collected all of the data over a 5-year period. The resultant large data set was analyzed, and Dr. Taylor and his group wrote and published several peer-reviewed papers on their findings. Dr. Taylor recently retired and moved to another state. The data set was archived on a WSU server. Dr. Taylor was granted emeritus faculty status upon his retirement; however, he continued teaching in environmental science at Southwest University as an adjunct faculty member and continued to stay active in his field by reading the literature. A year into his retirement, Dr. Taylor reads a paper just published by a WSU junior faculty member and her predoctoral trainee that has used a new modeling program to analyze parts of the large data set that he and his group built. The paper reports novel and valuable insights into forest climatology that were not possible with previously existing analytic algorithms. Although Dr. Taylor was unaware of the new algorithm, he is furious that he was not advised that the paper was being published, let alone being left off the authors' byline or not even mentioned in the "Acknowledgments" section. The three-state contract to WSU is mentioned in the acknowledgments as having supported the creation of the large data set, but the name of the principal investigator—Dr. Taylor—was not listed. Dr. Taylor writes to the WSU vice president for research demanding that his name be listed as an author by requesting that the journal publish a "correction" to the paper. He also threatens to file an allegation of plagiarism against the authors because their use of the data set without his knowledge represented an act of academic theft, or plagiarism. Comment on the implications of authorship, data sharing, and data ownership that impinge on this situation. What advice for action would you give to the vice president? Does Dr. Taylor's threatened plagiarism allegation have any merit? Why or why not? Are the junior faculty member and her trainee at fault for anything they did or didn't do?

4.8 Dr. Roy Osaka, a well-funded scientist, leaves Medium University to take a position at Large Medical Center University. Dr. Danielle LeBlanc, the departmental chair, assigns another faculty member, Dr. Carl Valdez, to Dr. Osaka's former office and lab. A few months later, Dr. Valdez comes across some of Dr. Osaka's files in a cabinet drawer. In looking through these materials, he discovers what looks to be a completed draft of a manuscript written by Dr. Osaka. What attracts Dr. Valdez's attention is that the title page lists Osaka's address as Large Medical Center University. No acknowledgment of Medium University is noted in the manuscript. Dr. Valdez is puzzled by this but does not take any action. Several months later, a paper authored by Dr. Osaka appears in a prestigious interdisciplinary journal. Dr. Valdez notes that the published paper is virtually identical to the manuscript he discovered in Dr. Osaka's former office. He has a good appreciation of the science involved and believes that Osaka could not have accomplished the work reported in the few months that he has been at Large Medical Center University. What's more, the acknowledgments in the printed paper thank a technician whom Dr. Osaka supervised at Medium University. Dr. Valdez believes that Dr. Osaka is attempting to demonstrate his research prowess by convincing his supervisors at Large Medical Center University that his research program is up and running at full throttle. In fact, however, it appears that the work was performed at Medium University. Dr. Valdez brings the departmental chair, Dr. LeBlanc, the manuscript and a copy of the published paper. He suggests that Dr. Osaka has committed scientific misconduct by deliberately falsifying information in the manuscript. Dr. LeBlanc comes to you, the department's resident expert in research ethics, and asks what she should do. What's your advice for her?

4.9 Suzanne Booth is recruited as a postdoctoral fellow in a laboratory where research centers on the cell biology of a specific mammalian cell type. Suzanne's training has been in eukaryotic gene cloning and molecular genetics; no such technology is available in this laboratory. Suzanne completely trains a senior-level graduate student working in the group. Under Suzanne's supervision, the student proceeds to build a complementary DNA (cDNA) library and isolates by molecular cloning a gene for a membrane protein. Several months later, a manuscript describing this work is prepared for submission. The principal investigator of the laboratory, Professor Jack Martin, and the student are listed as coauthors. Suzanne is listed in the "Acknowledgments" section of the paper. She is upset with this disposition and confronts Dr. Martin. Dr. Martin says that he has strict rules about authorship and that Suzanne's contribution was a technical one that does not merit authorship. Dr. Martin quotes from several different standards-of-conduct documents indicating that authorship must

be strictly based on intellectual and conceptual contributions to the work being prepared for publication. Technical assistance, no matter how complex or broad in scope, is not grounds for authorship. Does Suzanne have a case for authorship? Why or why not?

4.10 Dave Clubman completes his Ph.D. program and leaves the laboratory immediately to attend to personal matters. An important manuscript based upon his dissertation exists only in a preliminary draft. During the next year, Professor Holly Franks, his former advisor, attempts to contact Dave to complete the manuscript. After some months, Dr. Franks edits the manuscript, prepares the figures, and sends the updated version to Dave. Dave acknowledges receipt of the manuscript but provides no comments and does not sign a memorandum acknowledging consent to submit the manuscript. During this period, some results similar to Dave's are published by another laboratory. Dr. Franks and a postdoctoral fellow extend the work and prepare a new manuscript with Dave as first author and the postdoctoral fellow as an additional coauthor. The manuscript is sent to Dave by certified mail, but he does not provide any comments nor return a signed memorandum agreeing to submission for publication. A third party hears that Dave blames Dr. Franks for the delay and is trying to "give her a hard time." Dave was supported by federal funds, and his results were included in annual progress reports to the granting agency. Can Dr. Franks submit the manuscript and publish it if it is accepted by the journal? What should be the authorship on the paper? Should any comments be included in the "Acknowledgments" section?

Resources

Print

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Online

Selected instructions for authors or editorial policies

Journal of Bacteriology

http://jb.asm.org/site/misc/ifora.xhtml

Nature

http://www.nature.com/authors/gta.pdf

Phytopathology

http://apsjournals.apsnet.org/userimages/ContentEditor/1173286505152/phyto_author_instructions.pdf

Proceedings of the National Academy of Sciences of the United States of America

http://www.pnas.org/site/misc/iforc.pdf

Proceedings of the National Academy of Sciences Prior Publication Policy

http://www.pnas.org/content/96/8/4215.full

Science

http://www.sciencemag.org/site/feature/contribinfo/index.xhtml

Metrics

San Francisco Declaration on Research Assessment (hosted by the American Society for Cell Biology)

http://am.ascb.org/dora/

Organizations and associations

Committee of Publication Ethics

http://publicationethics.org/

Council of Science Editors (including *CSE's White Paper on Promoting Integrity in Scientific Journal Publications*, 2012)

http://www.councilscienceeditors.org/

Ethics Collaborative Online Resource Environment (Ethics CORE) website, a resource source for publications:

http://nationalethicscenter.org/resources/publications

International Committee of Medical Journal Editors website, where the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals may be accessed:

http://www.icmje.org/

The Office of Research Integrity website's resources on publications and authorship:

http://www.ori.hhs.gov/education/products/rcr_authorship.shtml

World Association of Medical Editors

http://www.wame.org/

Open access

Action Plan towards Open Access to Publications, from the Global Research Council:

http://www.dfg.de/download/pdf/dfg_magazin/internationales/130528_grc_annual_meeting/grc_action_plan_open_access.pdf

Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities

http://openaccess.mpg.de/Berlin-Declaration

Bethesda Statement on Open Access Publishing

http://dash.harvard.edu/handle/1/4725199

Budapest Open Access Initiative Declaration

http://budapestopenaccessinitiative.org/

Directory of Open Access Journals

http://www.doaj.org/

Harvard Open Access Project website (Peter Suber, director):

http://cyber.law.harvard.edu/hoap/Main_Page

Howard Hughes Medical Institute open public access policy

http://www.hhmi.org/about/policies/open-access/

Scholarly Open Access: Critical Analysis of Scholarly Open-Access Publishing is a blog created and maintained by Jeffrey Beall:

http://scholarlyoa.com/

Wellcome Trust open-access policy

http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTD002766.htm

Plagiarism detection software and use

CrossCheck

http://www.crossref.org/crosscheck/index.html

Deja Vu: a Database of Highly Similar Citations

http://dejavu.vbi.vt.edu/dejavu/

eTBLAST: a text-similarity based search engine

http://etest.vbi.vt.edu/etblast3/

iThenticate: online plagiarism detection software

http://www.ithenticate.com/

PubMed and related archives

PubMed, a biomedical literature citation database operated by the U.S. National Library of Medicine, National Institutes of Health:

http://www.ncbi.nlm.nih.gov/pubmed

PubMed Central, a green, open-access, full-text archive of biomedical and life sciences research publications operated by the U.S. National Library of Medicine, National Institutes of Health:

http://www.ncbi.nlm.nih.gov/pmc/

PubMed Central International, a collaborative effort between PubMed Central and organizations in other countries or areas (presently Europe and Canada) aimed at creating digital archives of the scientific literature at multiple global sites:

http://www.ncbi.nlm.nih.gov/pmc/about/pmci/

Europe PubMed Central, the website of the European PubMed Central research literature archive:

http://europepmc.org/

For funding agencies that require or encourage archiving of research articles supported by agency grants in Europe PubMed Central:

http://europepmc.org/Funders/

PubMed Central Canada research literature archive; the Canadian Institutes of Health Research (CIHR) requires that its grant recipients archive papers reporting their CIHR-supported research within 12 months of publication:

http://pubmedcentralcanada.ca/pmcc/

Scientific societies' guidance on authorship and publication ethics

American Chemical Society

http://pubs.acs.org/page/policy/ethics/index.html

American Psychological Association

http://www.apa.org/research/responsible/publication/index.aspx

Society for Neuroscience

http://www.sfn.org/member-center/professional-conduct/guidelines-for-responsible-conduct-regarding-scientific-communication

Other online resources

ClinicalTrials.gov, a registry and results database of clinical studies of human participants:

http://clinicaltrials.gov/

National Institutes of Health Office of Biotechnology Activities website, with links to the National Science Advisory Board for Biosecurity and Dual Use Research of Concern pages:

http://oba.od.nih.gov/biosecurity/about_nsabb.html

Retraction Watch, an independent blog created and maintained by Adam Marcus and Ivan Oransky that follows retractions of papers published in the scientific literature:

http://retractionwatch.wordpress.com/

Thomson Reuters Web of Science

http://thomsonreuters.com/thomson-reuters-web-of-science/

chapter 5

Use of Humans in Biomedical Experimentation

Paul S. Swerdlow and Francis L. Macrina

Overview • Are You Conducting Human Subjects Research? • The Issue of Informed Consent • IRBs • The IRB and the Informed Consent Issue • Research Exempt from the Federal Regulations • The IRB and Expedited Review • Human Experimentation Involving Special Populations • The Health Insurance Portability and Accountability Act (HIPAA) • Fetal Tissue and Embryonic Stem Cell Research • Conclusion • Discussion Questions • Case Studies • The Declaration of Helsinki • Resources

Overview

There are many important ethical issues in scientific endeavors, but none has been better codified than experimentation involving human beings as subjects. Much of early medicine undoubtedly involved experimentation, most of which was not regulated. In fact, the rules for experimentation with people were initially summarized in the Nuremberg Principles that came out of the Nuremberg war criminal trials at the end of World War II. These trials held accountable those involved in human experimentation performed without the consent of the subjects. Although largely of historical significance today, the Nuremberg Principles (also called the Nuremberg Code) provided the foundation for future guideline documents, most notably the Declaration of Helsinki (discussed below). The 10 Nuremberg Principles included statements about protection of human subjects; experimental design based on previous animal studies; careful risk-to-benefit analysis in the context of the importance of the problem being studied; performance of experiments only by scientifically qualified persons; subject-initiated withdrawal from the research at any stage; and investigator-initiated cessation of the experiment in the face of possible injury, disability, or death.

Scientific Integrity: Text and Cases in Responsible Conduct of Research, 4th ed.
by Francis L. Macrina

doi:10.1128/9781555818487.ch5