MANAGING ALLEGATIONS OF SCIENTIFIC MISCONDUCT:

A Guidance Document for Editors

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Office of Research Integrity
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I. Role of Editors in Responding to Scientific Misconduct

The role editors should play in responding to scientific misconduct has been articulated by their colleagues, asserted by two national reports, and demonstrated by the scientific misconduct allegations investigated by institutions and the Office of Research Integrity (ORI).

According to the International Committee of Medical Journal Editors (ICMJE), editors have a responsibility to pursue possible scientific misconduct in manuscripts submitted to or published in their journals and to publish a retraction of any fraudulent paper published in their journals. However, editors are not responsible for conducting a full investigation or deciding whether scientific misconduct occurred. Those responsibilities rest with the institution where the work was conducted or with the funding agency.[1] In England, a group of medical editors have formed a Committee on Publication Ethics (COPE) to "deal with breaches of research and publication ethics in our editorial capacities."[2]

A report on the responsible conduct of research issued by the Institute of Medicine in 1989 recommended that "journal editors should develop policies to promote responsible authorship practices, including procedures for responding to allegations or indications of misconduct in published research or reports submitted for publication."[3] Another report issued by the National Academy of

*A proposed new Federal definition of research misconduct was published on October 14, 1999, 64 Red. Reg. 55722. Once this definition is finalized and implemented by HHS, ORI will make changes to these guidelines as appropriate.

Sciences in 1992 on responsible science reiterated the earlier recommendation: "scientific societies and scientific journals should continue to provide and expand resources and forums to foster responsible research practices and to address misconduct in science and questionable research practices."[4]

The allegations of scientific misconduct investigated by institutions and ORI have indicated that editors need to participate in managing scientific misconduct issues. Since ORI was established in 1992, 78 publications involving scientific misconduct findings have required corrections or retractions of text, data, figures or the entire article.[5] Editors have also played a valuable role in informing ORI about suspect manuscripts and cooperating with investigations into alleged misconduct in the review process.

Editors have requested assistance from editorial groups and ORI in addressing possible scientific misconduct in submitted manuscripts.[6 7] In many instances, the editor or reviewer suspects that something is wrong with the data but is unaware of the appropriate procedures for addressing the problem. Editors sometimes return the manuscript to the author without confronting the possible scientific misconduct issue. However, this action does not prevent the data from being published. False or fabricated data may surface in the literature if an editor abdicates the responsibility of pursuing suspicious manuscripts. Because editors are expected to uphold and preserve the integrity of their journal, returning a manuscript that is suspect for scientific misconduct to its author is a disservice to the research community and may result in data being published that could adversely affect public health.

II. Purpose of Guidelines

The purpose of this document is to provide guidance to editors and their staff on reporting suspect manuscripts, facilitate the investigation of misconduct allegations, improve the correction of the literature, and promote research integrity. ORI is committed to working with editors to address possible scientific misconduct detected in manuscripts and published articles.

These guidelines do not establish any legal rights or cause of action by or against an editor, individual whistleblowers, respondents, or institutions, or the U.S. Department of Health and Human Services (DHHS) or any of its components, representatives or employees. If any provision of these guidelines is inconsistent with established rules and regulations under the Public Health Service (PHS) Act or other Federal laws, the latter shall prevail.

III. Definitions

"Allegation" means any disclosure, whether by written or oral statement or any other communication, to an institutional or DHHS official who receives the allegation while acting in his or her official capacity, that an individual has engaged in scientific misconduct.

"Office of Research Integrity (ORI)" means the office to which the Secretary of Health and Human Services has delegated responsibility for addressing scientific misconduct and research integrity issues related to PHS activities.[8]

"PHS" means the Public Health Service, a unit within DHHS which includes the Office of Public Health and Science and the following Operating Divisions: Agency for Health Care Policy and Research, Agency for Toxic Substances and Disease Registry, Centers for Disease Control and Prevention, Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, and the Substance Abuse and Mental Health Services Administration.

"PHS funds, funding, or support" means PHS grants, contracts, or cooperative agreements or applications therefor.

"Scientific misconduct" or misconduct in science means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data (42 C.F.R. 50.101).

"Suspect manuscript" means a manuscript submitted to or published in a journal which is suspected of including or being based upon falsified or fabricated data, results, or methodology or plagiarized text or ideas.

IV. Procedure for Handling Suspect Manuscripts

Handling a suspect manuscript is a delicate process, and ORI welcomes consultations during any stage of the publication process—pre-review, during review, post-review, or post-publication. ORI is committed to working with editors to address scientific misconduct as efficiently and thoroughly as possible.

Over the past eight years, ORI has worked with editors and institutional officials at various stages of the publication process to address scientific misconduct in the biomedical and behavioral literature. This assistance has occurred at the beginning of the review process when a manuscript is suspected of scientific misconduct, during peer review, and post-publication when a published manuscript has required a formal correction or retraction. This cooperation has been pivotal in protecting the integrity of PHS-funded research.

ORI recommends that editors take the following steps in handling a suspect manuscript:

1. Determine Funding Source

In order for editors to direct a suspect manuscript to the appropriate channels it is important to determine the research funding source. ORI is responsible for ensuring the integrity of PHS-funded research and is therefore authorized to receive an allegation if this funding is cited. There are situations in which the research being reported is funded by an agency other than the PHS, such as the National Science Foundation or the Department of Veterans Affairs. ORI can be contacted in these cases as it maintains a comprehensive listing of contacts, phone numbers, and addresses of other relevant Federal agencies that fund research. ORI also has contact information on some private funding sources of biomedical research. This information is readily available upon request.

2. Contact ORI

Editors should contact ORI or the awardee institution when it is believed that a manuscript is suspect for scientific misconduct and the research is supported by PHS funds. A list of ORI contacts is included at the end of this document.

ORI will often be an editor's preferred initial point of contact because ORI is able to provide unique and specialized technical assistance. ORI staff will be able to identify whether the suspicion concerns possible scientific misconduct according to the PHS definition and can offer advice on what steps should be pursued to address the possible misconduct.

ORI can facilitate communication between the editor and the institution that received the funding cited in the suspect manuscript. ORI maintains a database that includes the names of officials at 3,900 applicant or awardee institutions, including 181 in 33 foreign countries.[9] This information is available to editors who need to contact a particular institution. In appropriate cases, at the editor's request, ORI may refer the allegation directly to the research institution.

Technical assistance provided by the ORI staff, which includes eight scientist-investigators and four attorneys, is based on the experience gained in responding to approximately 1,900 allegations. From 1992 through October 1999, ORI closed 293 cases, including 87 inquiries and 206 investigations, and made 103 findings of scientific misconduct. The remaining 1,500 allegations were addressed but did not meet the jurisdiction criteria to be processed further.

3. Contact Responsible Institutional Official

By contacting the responsible official at the awardee institution, the editor or ORI activates an appropriate process for responding to allegations of scientific misconduct.[10] This process includes an inquiry to determine whether there is sufficient evidence of misconduct to warrant a formal investigation and, if necessary, an investigation to determine whether misconduct occurred, and if so, by whom. The respondent is given an opportunity to present evidence in defense of

the allegations. A diligent effort is made to maintain confidentiality and avoid conflicts of interest. If PHS finds misconduct, a full due process hearing is provided at the respondent's request.

V. Responding to ORI Requests for Assistance

In some cases, ORI may request that an editor provide data related to a manuscript that is the subject of an inquiry or investigation. Editors have access to the research record, which includes, but is not limited to, original manuscripts, correspondence, illustrations, computer generated data, and reviews. This research record may contain information critical to the evaluation of some allegations. Editors should retain the research record of manuscripts under investigation until the case is closed and all follow-up actions are complete. When the case is closed, the editor should retain or otherwise dispose of the research record under the journal's normal procedures.

In addition to the research record, ORI may ask for the name of a reviewer. Although editors routinely protect the confidentiality of their reviewers, special circumstances may warrant asking the reviewer to come forward voluntarily. Reviewers are urged to report any suspicions noticed in manuscripts they are reviewing. Suspicious evidence would include but is not limited to: text that is plagiarized, data that are too perfect, and results that do not coincide with the methods used to conduct the research. Although editors are the most likely to report the suspected manuscript, reviewers have also assisted ORI with investigations of research reported in manuscripts and published articles.

In seeking assistance from journals, ORI recognizes the need to maintain the confidentiality of the research record. In general, ORI neither acknowledges the existence of open cases nor releases any information about them. When a case is closed and misconduct is found, there is a public ORI announcement. Material is appropriately redacted to protect the privacy of individuals, other than the person found to have committed misconduct, before it is released. Appendix A provides information on three ORI cases which involved interactions with journals.

VI. Correcting the Literature

Persons found to have committed scientific misconduct in PHS-supported research may have administrative actions imposed on them by DHHS/PHS as well as by their institutions. One of the PHS administrative actions requires the correction or retraction of any article involved in the misconduct finding. Recipients of this action must submit a letter within 30 days to the pertinent journal requesting publication of the submitted correction or retraction. The requirement is noted on the PHS Administrative Actions Bulletin Board which lists all individuals who currently have an administrative action imposed on them.[11]

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

ORI may request that journals publish corrections or retractions resulting from scientific misconduct cases. While ORI does not have authority to require the journal to publish the retraction or correction, it can require the scientist who committed misconduct to submit the request. Besides PHS administrative actions, such requests may be initiated by the institution where the misconduct occurred or by a co-author of the questioned paper before ORI has completed its oversight review. If the request for a retraction is accepted by the editor, it should be labeled as such, appear in a prominent section of the journal, be listed in the table of contents, and include in its heading the title and citation of the original journal article.

VII. Helpful Editorial Policies

Experience in handling allegations of scientific misconduct indicates that there are several policies that editors could adopt that are likely to reduce the submission and publication of fraudulent manuscripts: (1) Reporting Suspect Manuscripts, (2) Procedures for Handling Suspect Manuscripts, (3) Co-author Signatures, (4) Submission of Data, (5) Guidelines for Reviewers, and (6) Corrections/Retractions.

1. Reporting Suspect Manuscripts

A key concern for some editors is whether there are legal consequences associated with forwarding a suspect manuscript to ORI. To ORI's knowledge, no legal action has ever been taken against an editor or journal as a result of an ORI misconduct case. However, the PHS regulation does not expressly shield editors from liability.[12] Thus, editors should consider taking preventative steps to protect themselves against potential problems.

As a specific step, editors should consider placing a notification in the journal's "Instructions to the Author." This notification would state that authors, by submitting a manuscript to the journal, will abide by the journal's policy and procedures for handling suspect manuscripts, including procedures for notifying the author's institution or ORI. This notification should also state that authors agree to cooperate with an institution or ORI[13] in investigating an allegation of scientific misconduct involving their manuscript or article. ORI also encourages research institutions to adopt similar policies which would direct institutional staff to cooperate with journals that are investigating suspect manuscripts or published papers.

The Council of Biology Editors, a professional association of editors of many of the world's leading biomedical journals, has examined this issue and its Editorial Policy Board recently drafted language for the purpose of aiding journals with this task. The policy statement reads:

> Should possible scientific misconduct or dishonesty in research submitted for review by the journal be suspected or alleged, the journal reserves the right to forward any submitted manuscript to the sponsoring or funding institution or other appropriate authority for investigation. The journal recognizes the responsibility to ensure that the question is appropriately pursued, but does not undertake the actual investigation or make determinations of misconduct.[14]

When journal editors issue a policy statement on this topic they may discourage authors from attempting misconduct by putting them on notice

that action will be taken if scientific misconduct concerns are detected. This notice also represents a preventative measure against possible legal actions when misconduct arises.

2. Procedures for Handling Suspect Manuscripts

Developing procedures for handling suspect manuscripts will guide the editorial staff and reviewers in handling this issue. The absence of such procedures reduces the likelihood that misconduct will be reported when detected. Instead, the suspect manuscript is more likely to be rejected and returned to its author, thereby creating the possibility that it will be published elsewhere.

3. Co-author Signatures

Some misconduct cases have involved the publication of manuscripts without the knowledge or consent of all named co-authors. Requiring all co-authors to sign-off on the manuscript validates their accountability for the content of the manuscript and reduces the probability that a fraudulent manuscript will be submitted.

4. Submission of Data

Respondents in several misconduct cases have been unable to produce the data reported in their manuscripts or articles. Some journals require authors to place the data supporting their manuscripts in depositories. Requiring that the data supporting all submitted manuscripts be deposited may not be feasible. However, authors could be explicitly informed that their data may be requested during the review process or if questions arise following publication.

5. Guidelines for Reviewers

In some cases, reviewers have failed to maintain the confidentiality of the review process, have stolen ideas or plagiarized text from the manuscripts under review, or have failed to report suspect manuscripts. Guidelines can be developed which explicitly inform reviewers of their responsibilities. Journals that already have such guidelines may want to review their adequacy.

6. Corrections/Retractions

As noted in Section I, 78 publications have required correction or retraction because of their involvement in findings of scientific misconduct since 1992. Others were voluntarily corrected or retracted during an inquiry or investigation by the research institution or one or more co-authors. The response by editors to these retraction requests has varied from publication to no action. A useful policy would specify who may request a correction or retraction, the criteria for determining whether a correction or retraction would be published, and the form, content and location of the notice. Editors are urged to incorporate the standard for retractions suggested by the ICMJE in their policy on corrections and retractions:

> The retraction, so labeled, should appear in a prominent section of the journal, be listed in the contents page, and include in its heading the title of the original article. It should not simply be a letter to the editor. Ideally, the first author should be the same in the retraction as in the article, although under certain circumstances the editor may accept retractions by other responsible persons. The text of the retraction should explain why the article is being retracted and include a bibliographic reference to it.[15]

VIII. Conclusion

Editors are unavoidably involved in the effort being made by institutions and PHS to respond to allegations of scientific misconduct. Editors are not required to investigate allegations of scientific misconduct, but they do have a responsibility to ensure that significant suspicions are reported to those able to conduct inquiries and investigations. Their responsibility has been articulated by their colleagues, prescribed by two national reports, and validated by the handling of scientific misconduct cases since 1992.

ORI offers editors assistance in handling allegations and identifying the appropriate officials in Federal agencies and research institutions to contact about such allegations. On the other hand, ORI requires the assistance of editors in investigating allegations, correcting the literature, and promoting research integrity. Editors can promote research

integrity by developing policies, procedures, guidelines or requirements on (1) reporting suspect manuscripts, (2) handling suspect manuscripts, (3) coauthor signatures, (4) submission of data, (5) review of manuscripts, and (6) submission and publication of corrections and retractions.

REFERENCES

1. "Uniform requirements for Manuscripts Submitted to Biomedical Journals." *Annals of In Med*, 126(1) 45, 1997.
2. The COPE Report 1998. A. Williamson and C. White, Eds. London: BMJ Books, p. 1.
3. The Responsible Conduct of Research in the Health Sciences: Report of a Study by the Committee on the Responsible Conduct of Research. Washington, D.C.: The National Academy Press, 1989, p. 37.
4. Responsible Science: Ensuring the Integrity of the Research Process. Panel on Scientific Responsibility and the Conduct of Research. Washington, D.C.: The National Academy Press, 1992, p. 16.
5. ORI made 103 scientific misconduct findings from June 1992 to October 31, 1999.
6. "Time to face up to research misconduct." R. Smith. *BMJ*, 312:789-790, 1996.
7. *Fraud and misconduct in medical research*. S. Lock and F. Wells, Eds. London: BMJ Publishing Group, 1996.
8. Final decisions on PHS scientific misconduct will be made by the Assistant Secretary for Health, subject to appeal to the Departmental Appeals Board.
9. Data as of October 1999.
10. Each institution that applies for or receives PHS research support must create and follow an administrative process for responding to allegations of scientific misconduct that complies with the regulation (42 C.F.R. Part 50, Subpart A).
11. The PHS Administrative Actions Bulletin Board may be accessed through the ORI web site at http://ori.dhhs.gov.
12. 42 C.F.R. Part 50, Subpart A. However, there may be a qualified privilege under State and common law to report alleged misconduct to responsible institutional or governmental officials. See ORI Position Paper #1, "The Whistleblower's Conditional Privilege to Report Allegations of Scientific Misconduct," December 1993 (available on ORI's web site at http://ori.dhhs.gov).
13. Recent HHS policy changes assign responsibility for direct HHS investigations of scientific misconduct to the Office of Inspector General, not ORI. However, ORI continues to perform initial intake on allegations, make referrals to the extramural institutions or OIG, and perform oversight review when the investigation is complete. Thus,

ORI remains the initial point of contact for questions about suspect manuscripts.

14. Personal communication to ORI staff from chair, Editorial Policy Board, CBE, July 1998. See also, note 1, supra.
15. Uniform Requirements for Manuscripts Submitted to Biomedical Journals and Supplemental Statements from the International Committee of Medical Journal Editors, 1994, p. 25.

Appendix A

ORI Case Examples of Suspect Manuscripts

Case #1

While reviewing a manuscript for publication, a reviewer for a journal believed that the experiments reported could not have been conducted as described and that several of the figures had been falsified. The reviewer notified the editor, who informed the author that the paper needed to be investigated due to questions regarding the validity of the data. The editor told the author that if the author did not inform a supervisor of the data validity concern then the editor would do so. The author reported the matter to the supervisor, who in turn contacted the appropriate institutional official. The institutional official addressed the validity concern and contacted the editor, who provided all the materials from the journal's manuscript file for review during an inquiry by the institution and an investigation by the ORI. The editor's correspondence was particularly helpful in understanding whether the scientist had made a mistake or was deliberately deceptive. The editor protected the confidentiality of the reviewer who detected the alleged scientific misconduct. However, as the investigation progressed the editor obtained the reviewer's permission to reveal his name to ORI. This disclosure was important because ORI was considering the reviewer as a potential advisor for the investigation. This was not done because of the reviewer's prior involvement in the matter. The editor played an important role because he was able to preserve the evidence and guarantee the authenticity of the files.

Case #2

ORI contacted an editor after receiving documentation about falsified research in three versions of an unpublished manuscript. The editor initially was reluctant to cooperate with ORI. However, the editor recognized that he possessed the primary evidence in the manuscript processing file and agreed to contact the institutions where the research had been conducted. ORI contacted the institutions and informed them that the editor would contact them. The cooperation of the editor enabled the institutions and ORI to prove data falsification.

Case #3

The possibility that data had been fabricated or falsified in a submitted manuscript surfaced when an editor advised the corresponding author about a reviewer's concerns regarding the authenticity of a figure. When other factors confirmed the concerns, the corresponding author confronted the first author who admitted to fabricating major portions of the relevant research and related research publications. The institution where the research was conducted and the ORI were notified of the allegations. The institution conducted a formal investigation of the allegation and found extensive falsification and fabrication and ORI concurred. Retractions and corrections of the relevant publications were made at the conclusion of the investigation.

ORI Information and Technical Assistance

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