Office of Research Integrity: a Reflection of Disputes and Misunderstandings
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Each year, the U.S. Public Health Service (PHS) provides billions of dollars to support over 30,000 extramural research grants to more than 2,000 institutions in the U.S. and other countries. The Office of Research Integrity (ORI) is responsible for protecting the integrity of the research supported by the grants awarded for the PHS extramural research program. One of its responsibilities includes monitoring investigations into alleged or suspected scientific misconduct by institutions that receive the PHS funds. However, not all of the alleged or suspected scientific misconduct meet the the PHS definition of scientific misconduct. Among the wide range of allegations that the ORI receives are those that are ultimately determined to be authorship disputes. This article will report on ORI's functions and review some of the commonly reported allegations that do not constitute scientific misconduct according to the PHS definition.

Key words: authorship; ethics in publishing; fraud, scientific; intellectual property; mentorships; ownership; plagiarism; research misconduct; scientific misconduct; United States Office of Research Integrity

Scientific misconduct became a public issue in the United States in 1981 when the Investigations and Oversight Subcommittee of the House Science and Technology Committee held the first hearing on the emerging problem. The hearing was prompted by the public disclosure of scientific misconduct cases at four major research centers in 1980. Some twelve cases of scientific misconduct were disclosed in the United States between 1974-1981. Congressional attention to scientific misconduct was maintained throughout the 1980s by additional allegations of scientific misconduct and reports that the National Institutes of Health (NIH), universities, and other research institutions were inadequately responding to those allegations.

The U.S. Congress took action in 1985 through the Health Research Extension Act. The Act required institutions seeking federal research grants to establish "an administrative process to review reports of scientific fraud" and "report to the Secretary any investigation of alleged scientific fraud which appears substantial." To carry out the law, the Public Health Service (PHS) in March 1989 created the Office of Scientific Integrity (OSI) in the Office of the Director at NIH, and an Office of Scientific Integrity Review (OSIR) in the Office of the Assistant Secretary for Health. In June 1992, these offices were consolidated into the ORI (Office of Research Integrity), and the Office of Health and Human Services (HHS) established a hearing opportunity for all scientists formally charged with misconduct.

Office of Research Integrity Functions
ORI carries out its responsibility by (a) developing and promulgating policies, procedures, rules, and regulations; (b) administering an assurance program; (c) reviewing investigations conducted by applicant or awardee institutions; (d) conducting investigations at applicant or awardee institutions and in the Public Health Service intramural research programs; (e) presenting misconduct findings in administrative hearings before the HHS Departmental Appeals Board (DAB); (f) conducting educational, training, and technical assistance programs, (g) conducting studies and developing guidelines; and (h) promoting research integrity.

Develops Policies, Procedures, Regulations
The Division of Policy and Education (DPE), is responsible for developing policies, procedures, rules, and regulations for responding to allegations of scientific misconduct occurring in research supported by the Public Health Service extramural and intramural research programs. These policies, procedures, rules, and regulations cover a wide spectrum of subjects: definitions, the investigative process, the protection of complainants, the rights of the respondent, reporting requirements, appeal procedures, implementation of administrative actions, standards of proof, records management, and public disclosure of information. For instance, the Federal regulation defines misconduct or misconduct in science as "...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.” (1).

Administers an Assurance Program

The ORI administers an assurance program mandated by a Federal regulation. The Federal regulation requires each institution that applies for or receives support under the Public Health Service Act to file an assurance with ORI that it has established an administrative process for receiving, reviewing, investigating, and reporting allegations of misconduct; that this administrative process meets the requirements of the Federal regulation, and that it will comply with this administrative process when responding to allegations of scientific misconduct. In addition, each institution must submit annually aggregate information on allegations received and inquiries and investigations conducted.

In administering the assurance program, the ORI determines if an institution is eligible to receive funding by ascertaining whether the institution has an active assurance on file; checks the administrative processes to see whether they comply with the Federal regulation; reviews inquiries and investigations conducted by the institution to determine whether they comply with the administrative process and the Federal regulation, and institutes compliance actions when violations are detected. As of December 31, 1998, there were 3,697 active assurances on file in ORI, including 168 from 32 foreign countries.

Reviews Institutional Investigations

Because institutions have the primary responsibility for responding to allegations of scientific misconduct, the ORI role in most investigations is usually that of reviewing the institution's investigative report. Responding to an allegation of scientific misconduct involves a two-step process; an inquiry, and if necessary, an investigation. An inquiry is a preliminary examination of an allegation to determine whether the allegation has sufficient substance to warrant an investigation. The Federal regulation requires institutions to conduct an inquiry immediately upon receipt of an allegation. Complaintants usually make their allegations to the institution employing the respondent although allegations may be made directly to ORI. In such cases, ORI normally asks the institution to conduct an inquiry. The inquiry should be completed in 60 days. An investigation is a formal examination of an allegation to determine whether misconduct has occurred, who engaged in misconduct, and the extent of the misconduct. An institution must begin an investigation within 30 days of completing an inquiry. The institution must submit its investigative report to ORI within 120 days of initiating the investigation.

The ORI generally does not review inquiries because an institution is required neither to inform ORI that an inquiry is underway nor to submit a report at its conclusion. The ORI reviews inquiry reports under three conditions: (a) the ORI requested the institution to conduct the inquiry because the allegation was made directly to the ORI; (b) the ORI had reason to believe that the institution did not conduct the inquiry properly; or (c) the institution submitted the inquiry report to ORI as part of the report of an investigation.

The ORI reviews all investigations. Institutions must inform the ORI when they begin an investigation and submit a report at its conclusion. To be within ORI's jurisdiction, the alleged misconduct must involve the Public Health Service supported research or an application for the Public Health Service support, and fall within the Public Health Service definition of scientific misconduct. If these requirements are fulfilled, the ORI reviews the case to determine whether the investigation was thorough, fair, and objective and whether the evidence supports the findings. At this point, the ORI may accept or reject the findings, ask for additional information, request further investigation, or begin its own investigation.

The ORI reviews all inquiries conducted by the Public Health Service agencies in response to allegations of scientific misconduct in the Public Health Service intramural research programs. The Division of Research Investigations is responsible for reviewing inquiries and investigations into allegations of scientific misconduct.

Conducts Investigations

The primary responsibility for conducting an investigation rests with the institution, but the ORI will conduct its own investigation when requested by an institution, when the institution is unwilling or unable to conduct an investigation, when an institution refuses to provide requested information or perform additional investigation or when the institutional investigation is insufficient. When conducting an investigation, ORI may seek the assistance of one or more scientists to ensure that the necessary expertise is available.

The ORI conducts all investigations of scientific misconduct in the Public Health Service intramural research programs. Individuals found to have committed scientific misconduct by an institution or the ORI are included in the Public Health Service Alert system. This is a Privacy Act system of records.
which is intended to inform, only on a need-to-know basis, the Public Health Service agency personnel relevant to findings of misconduct.

The Division of Research Investigations conducts investigations into allegations of scientific misconduct in the Public Health Service extramural and intramural research programs. The Public Health System Alert system is maintained by the Assurance Program within the Division of Policy and Education.

Presents Misconduct Findings in the Hearing Process
When the ORI concludes a case, it notifies respondents of its findings. In cases in which misconduct is found, respondents are informed that they have 30 days to request a hearing before the Departmental Appeals Board (DAB) on the findings and proposed administrative actions. During a hearing, respondents have an opportunity to be represented by counsel, to question any evidence and witnesses presented by ORI, and to present evidence and witnesses in rebuttal to the findings and proposed administrative actions. Once the DAB has heard both the ORI and the respondent, the DAB then makes its decision. This decision is the final Public Health Service decision.

Conducts Educational, Training, and Technical Assistance
ORI sponsors and co-sponsors a variety of education, training, and technical assistance efforts in order to promote research integrity. These efforts are also done in collaboration with scientific societies and professional associations. In 1998 ORI staff participated in 25 presentations at conferences, workshops, or meetings addressing research integrity issues in the U.S. and abroad. The topics addressed have pertained to a range of research integrity issues. Some of the workshop sessions have evolved into publications appearing in scholarly journals such as the Journal of Science and Engineering Ethics.

Studies and Guidelines
Promoting research integrity has also been achieved through conducting studies and developing guidelines for the research community. ORI has commissioned research studies and has conducted studies based on information available from in-house. Studies already conducted included: "Consequences on Being Accused of Misconduct", "Consequences of Whistle Blowing" and "Studies on Inquiry Reports Not Submitted to ORI". These studies provide important information for policy and education efforts.

In addition to conducting studies, ORI has developed guidelines for its constituents as a way of providing technical support and policy guidance. Topics which have been developed or are under development include: (a) Guidelines for Responsible Whistleblowing; (b) Guidelines for Respondents Accused of Misconduct in Science; (c) Guidance for Journal Editors; and (d) Guidelines for Institutions Investigating Allegations of Possible Misconduct in Clinical Research.

These documents have been developed in response to requests from constituents or are issues that ORI staff address frequently.

Promotes Research Integrity
Besides investigating allegations of scientific misconduct, the ORI works to reduce the incidence of misconduct by promoting research integrity in collaboration with universities, medical schools, professional associations, and scientific societies. ORI encourages these groups to submit proposals for developing conferences or workshop that address either dealing with scientific misconduct allegations or the promotion of research integrity.

ORI also publishes a quarterly newsletter that is distributed to over 3,000 readers. The newsletter and other ORI publications and documents are available on the ORI internet website at (http://ori.dhhs.gov). Promoting research integrity is important for preserving the trust within the research community and the public. Without integrity, progress can be thwarted easily and public health could be at risk.

Allegations outside of the Public Health Service
Allegations of scientific misconduct are assessed based on the criteria established by the Public Health Service definition of scientific misconduct. Although allegations of falsification and fabrication are the most common scientific misconduct finding reported, ORI receives many allegations that do not meet the Public Health Service definition of scientific misconduct. Misunderstandings about the Public Health Service definition have contributed to plagiarism allegations that are later determined to be authorship disputes. Authorship disputes comprised approximately 22% of the 166 allegations in 1997, and 27% of the 112 allegations that ORI received in 1998. Typically, a complainant submits an allegation of scientific misconduct believing it to be one of plagiarism; however, upon review ORI often determines that the alleged misconduct is better characterized as an authorship dispute, rather than plagiarism. One reason for this confusion may be that ORI's interpretation of plagiarism under the Public Health Service definition of scientific misconduct has a more narrow scope than the term plagiarism as used more casually in the non-regulatory context.
As a general working definition, "ORI considers plagiarism to include both the theft or misappropriation of intellectual property and the substantial unattributed textual copying of another's work. It does not include authorship or credit disputes. The theft or misappropriation of intellectual property includes the unauthorized use of ideas or unique methods obtained by a privileged communication, such as a grant or manuscript review." (2).

As noted in the ORI Newsletter, "many allegations of plagiarism involve disputes among former collaborators who participated jointly in the development or conduct of a research project, but who subsequently went their separate ways and made independent use of the jointly developed concepts, methods, descriptive language, or other product of the joint effort. The ownership of the intellectual property in many such situations is seldom clear, and the collaborative history among the scientists often supports a presumption of implied consent to use the products of the collaboration by any of the former collaborators." (2). Because institutions are the recipients of the Public Health Service funds, ORI considers it the institutions' responsibility to manage the funds they receive and mediate disputes that may arise over authorship controversies.

Many of the "plagiarism" allegations submitted to the ORI are found to be authorship or credit disputes between collaborators or former collaborators. Examples of such disputes include: misappropriation of collaborators' ideas, disagreements over who should be an author, or the order of authorship. Other nuances of this issue include questions of whether consent must be obtained in order for a collaborator to publish independently from his or her research team and whether a member of a research team can publish conflicting analyses.

These disputes often involve persons in some form of training who challenge the mentor over the ownership of research ideas which results in arguments over authorship priority and status. Although these situations are not considered by ORI to fall under the Public Health Service definition of scientific misconduct (2), their existence highlights the lack of generally accepted standards regarding the mentor/trainee relationship in the research training environment. In addition, these conflicts often become personal. Establishing explicit standards that require each author to take responsibility for the co-authorship listed on the manuscript could prevent misunderstandings before they escalate into caustic and lengthy legal disputes.

Another type of authorship dispute brought to ORI's attention relates to the issue of "inventorship". Controversies linked to proprietary benefits stemming from inventions of drugs, vaccines, biologic agents, or chemical syntheses have been known to evolve into expensive and time consuming investigations at institutions. These types of disagreements should not be mediated by journal editors or the federal government. Usually they are referred to the author's institution for resolution. Yet inventorship disputes can pit one institution against another, or an institution against its employees so that it is particularly hard to convince a complainant that an institution can be fair, when it has a perceived financial conflict of interest in the matter.

Some researchers are not aware of the expectations and standards of the journals, professional societies, or even their own institutions. In their 1993 publication, ORI investigators Fields and Price noted that "academic politics or cultural bias about appropriate roles based on age, gender, or position in the departmental hierarchy sometimes enter into authorship decisions. With more and more attention to written guidelines, it may be that some of the less valid claims would not be made if a process of rational discussion and negotiation was a recognized step in publication decisions" (3). It is easy for an author to plead ignorance when generally accepted standards do not exist. However, such a plea does little to appease those who are party to an authorship dispute. To avoid such conflicts it is highly advisable to address authorship issues prior to writing the initial draft of a manuscript, or even prior to initiating a collaborative research effort. This should promote a clearer understanding among co-authors about their authorship responsibilities and thereby reduce the possibility of future conflicts.

Cultural Considerations

The United States is a training ground for scientists from around the world. Thus, misunderstandings can arise when there is not a global consensus about acceptable criteria for authorship. Cultural misunderstandings may be at the root of some plagiarism allegations and can be particularly contentious. For example, the research culture in the U.S. does not condone copying of anyone's published works without proper attribution. Yet in some cultures "copying" a mentor's work is a form of respect. Conversely, there may be cultural differences regarding a mentor's right to use his student's data. Thus, cultural differences can add to confusion about what constitutes plagiarism versus what is an acceptable practice in an international academic research laboratory (4).

In addition to differences among scientists' attitudes, publishing has changed dramatically in the last decade because of technological innovation. Publishing is now more accessible to individuals. Even so, there are no uniform standards in the publishing industry that address authorship accountability. In
her book "Stealing into Print", Marcel LaFollette maintains that "The same technology that makes life easier for the honest researcher may also assist the dishonest one. Rapid and easy dissemination will facilitate plagiarism, the fabrication of data (including databases), and attempts to obscure authorship or authenticity. In addition, the increased use of computers to mechanize team written reports may influence how teams assign and accept responsibility for the integrity and accuracy of the entire text." (5).

Today's information technologies are capable of crossing international boundaries and highlight the need for publishing standards that address the accountability and responsibility that come with authorship. Thus, the challenge for ensuring the integrity and quality of publications increases as the technology of managing and transmitting information improves. The use of the Internet, copying and forwarding texts at incredible speed produce challenges not previously addressed in the publishing culture.

Lessons Learned
Reviewing allegations of scientific misconduct that do not meet the criteria of the Public Health Service definition is time consuming because they often involve questions of honest differences in interpretations or judgments of data which are specifically excluded under the Public Health Service definition. Collaborative research efforts in multiple labs, the varying academic politics and cultural biases, and the advances in information technology, all present unique challenges for ORI and the research community. As research among various countries increases, so will the efforts needed to promote research integrity.

The most effective method for reducing those allegations previously discussed is through education – a responsibility for ORI, universities, medical schools, professional associations, and scientific societies. ORI is committed to developing strong partnerships with these groups in order to promote research integrity through greater awareness. These efforts are particularly important as research crosses continents and cultures.

Conclusion
Research integrity is a vital component of the research process. The number of scientific misconduct findings and observations made and lessons learned about those allegations falling outside of the Public Health Service definition have contributed to a regulatory office that has been able to share its findings and observations with the research community in a constructive manner. In summary, further education and outreach is needed to promote research integrity in order to increase awareness and decrease erroneous allegations and misunderstandings within the research community both in the U.S. and abroad.

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