Issues on Research Integrity: A Perspective

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This paper discusses several key issues that are relevant to the integrity and success of the biomedical research enterprise. Attention to these issues will improve research outcomes and reduce negative consequences in research. Subjects addressed include normative practices in research; the importance of quality data; mentoring of young scientists; how to proceed when a member of the scientific community discovers misconduct or other breaches of integrity; and the level of harm to public confidence in research due to misconduct and lack of transparency in research findings. Exp Biol Med 231:1262–1263, 2006

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Questionable Practices

Over the past 10 or more years, a number of studies have shown that graduate students, postdoctoral fellows, and more senior scientists have engaged in questionable research practices that undermine the credibility and usefulness of research findings, such as dropping data points based on a "gut feeling" (15%), inadequate record-keeping (27%), and overlooking of others' use of flawed data or questionable interpretation of data (13%). Too many scientists cut corners and manipulate data to get desired results. A recent paper in *Nature* (1) confirmed these problems in postdoctoral fellows and RO1-funded investigators. The Office of Research Integrity (ORI) believes these actions undermine the credibility of the research enterprise and the reputation of scientists. Since the American public relies on research to create new products and therapies to improve public health, undermining the public trust in research will lead to more litigation, a lower confidence level in new research findings, and possibly greater regulation and a slower increase in funds for research. ORI encourages the research community to take steps to revitalize trust in research and in the scientists and institutions that conduct the research.

Importance of the Research Data

ORI views the research data as the key element in making progress in research. If the data are recorded and kept in an appropriate manner and interpreted and reported fairly and accurately, including in publications, then scientists, medical providers, and the public are able to rely on the data and make appropriate conclusions about the scientific findings generated from the data. Scientists and institutions that ignore these principles undermine the scientific enterprise. Unreliable data waste public funds and scientific effort and mislead the public and other scientists. ORI considers correction of the scientific literature an important part of its mission when publications are undermined by falsified and fabricated data. Research institutions and scientific journals also endeavor to correct the literature when they determine that papers are false or unreliable.

Training the Next Generation of Scientists

ORI believes that mentoring continues to be a very important part of the training of young scientists and in most cases probably the most important part. However, with changes in the research enterprise, with larger laboratories and more interdisciplinary teams of scientists, frequently off-site or internationally based, it is no longer possible for the Principal Investigator (PI) or lab chief to provide supervision or mentoring to all the team members. Thus, quality control by the senior scientist in the study is no longer feasible in many cases. Therefore, ORI believes that other ways of training scientists may be needed to supplement mentoring. Over the past 5 to 10 years, ORI has invested many staff hours and hundreds of thousands of dollars in creating educational materials in the responsible conduct of research (RCR) (2) for all scientists, with particular focus on the younger scientists. One publication has now been translated into Japanese and Chinese, and other translations are likely. In addition, a number of web-based RCR products are available worldwide on a variety of topics relevant to research integrity and improving research quality. ORI has also funded the Council of Graduate

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Schools to support development of RCR education programs in 10 graduate schools and additional affiliated schools. The long-term goal for CGS is to institutionalize RCR education in all graduate programs. A study conducted by ORI in 2002 on 6000 NIH-funded scientists indicated that the PI or lab chief provided adequate or better mentoring about 75% of the time. However, a subset of the PIs/lab chiefs (approximately 25%) only held lab meetings about 12 times or less a year, spent less than one hour a week supervising each trainee, and reviewed lab notebooks approximately three times a year. In ORI's view, these less involved scientists are providing insufficient time for the training of young scientists.

Filing a Complaint: Breaches of Research Integrity

ORI believes that one of the best approaches to protect complainants is prevention. The research institution should provide confidential consultations to scientists and administrators who have concerns about research misconduct, improper data, authorship disputes, etc. If the concerns are valid and deserve an institutional response, then the institution should pursue the matter. Frequently, the institutional research integrity officer or other staff in the Vice President for Research Office assumes this responsibility. If the individual does not have sufficient information to file an official complaint, has misinterpreted the criteria for official action (e.g., research misconduct, human subjects violation, etc.) or for some other reason the complaint is not well grounded, the individual has avoided the potential serious risk of filing a weak or incorrect complaint that might lead to negative outcomes for the complainant. ORI is also available to provide confidential advice to individuals who believe research misconduct or other related integrity matters have occurred. ORI takes a special interest in protecting complainants because of its regulatory responsibility, but also because it recognizes the importance of protecting individuals who come forward with legitimate complaints. In the Poehlman case which became public in 2005 (3), a few individuals came forward with information that resulted in one of the biggest misconduct cases ever in the U.S. They were threatened with retaliation and counter-allegations by the respondent. ORI considers such individuals to be heroes in science who risk their careers to protect the integrity of science. Their actions remove dishonest scientists from the system, identify fraudulent research that should be removed from the science literature, and honor and support the great majority of scientists who work diligently to produce honest and useful results.

The Importance of Research Misconduct

Individual cases of research misconduct can damage the reputation of the research enterprise and public confidence therein, especially if they involve clinical research or cause a threat to human subjects. For example, the Gelsinger case at the University of Pennsylvania (4) created long-lasting concerns about the safety and integrity of gene therapy research even though formal misconduct was not involved. Likewise, recent safety concerns about pharmaceutical products, such as Vioxx (5), raised widespread concerns among the patient populations that were using the affected products. In addition to the serious safety concerns for patients, such instances create enormous financial risks to the research enterprise and individual companies due to liability concerns and litigation costs. As a health care consumer, I value honesty, accuracy, and transparency in getting valid information about health care, including products based on research. If the risks are known and the information about those risks are accurate and communicated to the patient population and medical providers in a fair way, I believe the consumer will tolerate mistakes that occur much more readily than if the risks are unknowable, kept secret, or obfuscated. Furthermore, accuracy and transparency should reduce liability and litigation risks against research institutions, individuals, and companies. ORI does not consider research misconduct alone to be the most important cause of reduction of trust and confidence in the research enterprise, but it is one element. But looking generically at research misconduct, lack of product safety, and lack of full disclosure and accuracy, all of these matters taken together can do significant harm to the research enterprise and public trust. Reducing these risks, and the accompanying harm, should be a major goal of the research enterprise during the next decade.

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4. http://www.sskrplaw.com/publications/bioethics.html.
5. http://www.fda.gov/cder/drug/infopages/vioxx/default.htm.