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Establishing and Maintaining Research Integrity at Academic Institutions: Challenges and Opportunities

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Abstract

Integrity and trust are essential attributes of medical researchers. Research misconduct represents clear and present dangers to academic institutions and their faculty, residents, students, and staff

To achieve and maintain public trust, medical researchers must achieve and maintain research integrity. To do so requires synchronicity and collaboration between, as well as within all academic institutions. Substantial failures to maintain research integrity by institutional leadership will lead to increasing demands to do so from the funding organizations as well as the general public. This, in turn, will lead to avoidable consequences of substantial penalties, financial and otherwise, adverse publicity and reputational damage.

Researchers must self-regulate to avoid pitfalls, including those created by changes in the medical care delivery system that have decreased the influence of health care providers and increased the influence of outside legal and business interests. Our common goal should be to return public trust

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Keywords

research integrity; academic institutions; transparency

Introduction

Integrity and trust are essential attributes of medical researchers. Research misconduct represents clear and present dangers to academic institutions and their faculty, residents, students, and staff. As one index of research misconduct, the number of articles retracted by journals has continued to increase, initially, due to fraud but more recently, through efforts to detect and expose the problem.[1]

At one end of the spectrum, research misconduct encompasses fabrication, or making up data, falsification, or manipulating data, and plagiarism, or the appropriation of the work of others. Dishonesty encompasses more subtle aspects such as reshaping data and withholding analyses which appear less favorable, as well as other situations where the lines between bending and breaking the rules are less clear. The magnitude of the problem is highlighted by the reality that many academic institutions throughout the United States are currently undergoing regulatory research oversight investigations. Such investigations are utilizing taxpayer dollars, achieving adverse publicity, levying substantial fines, and eroding reputations as well as public trust. Despite an urgent need to detect and address misconduct in timely manners, we must not allow the violations committed by a minority of researchers to detract from the growing focus on efforts to improve the overall quality of the research process carried out by the vast majority.

At the other end of the spectrum, research integrity focuses on the many positive attributes that should be sought and maintained by academic institutions as well as their faculty, staff, and trainees. This includes transparency, rigor, and reproducibility, already being practiced by the vast majority as well as avoidance of misconduct, fabrication, falsification, and plagiarism, practiced by the small minority. Research integrity starts with investigators who share the guiding principles of honesty, openness, and accountability and who provide scientific and ethical mentorship to their trainees. Institutions should create a culture of research integrity, which incorporates formal training, benchmarking, and rewards for continuing assessments and quality improvements across the research continuum. Finally, as institutions and their leaders, as well as their researchers, compete for increasingly limited resources and face growing challenges with evolving technologies, broad consensus is required across the research enterprise which encompass the funding agencies and medical journals as well as all academic institutions, their faculty, staff and trainees to address these increasingly major clinical, ethical, and legal challenges.

In this manuscript, we review the current challenges and highlight opportunities for academic institutions to achieve and maintain research integrity.

Research integrity encompasses accountability for all scientific and financial issues. Scientific issues include human subjects' protection, investigator accountability, grant submission, design, conduct, analyses, and interpretation of findings, as well as oversight of colleagues and students. These challenges include facilities and safety of equipment and laboratories as well as, where indicated, environmental health and safety and animal care. Research integrity can be achieved when institutions strive for and maintain compliance, optimally, collaboratively, and collegially.

Research compliance assures adequate accountability, avoids liability, and encompasses all activities that support, coordinate, manage, and monitor the risks associated with research in accordance with federal, state, and local laws and regulations. Failure to enforce rigor at the institutional level may occur initially through lack of recognition but then, becomes more alarming if it continues after appropriate concerns have been raised. A lack of transparency and failure to address serious scientific and procedural non-compliance raises equally serious ethical and legal concerns. For example, one academic institution recently paid $112 million to settle a whistleblower lawsuit after federal prosecutors said a research technician's fake data landed millions of dollars in federal grants[3]. The United States government alleged that, between 2006 and 2018, the institution knowingly submitted falsified/fabricated data to federal agencies in 30 grants. Initially, the narrowness of the reported findings by the Office of Research Integrity as well as the public statements by the leadership sent an erroneous message that senior and junior investigators and their staff, as well as university leaders and administrators, would not be held accountable for their failures to oversee research integrity. This represented a missed opportunity for investigators, universities, and the public to learn why systems of oversight may fail, and how to prevent such failures in the future. Such unfortunate occurrences, especially when compounded by inadequate responses from institutional leadership, who bear the ultimate responsibility, further emphasize the need to protect the integrity of research and the human subjects from indignities or other harms. These responsibilities include serving as role models for students. While the primary responsibility for research integrity begins with the principal investigator and extends to the investigating team, those in positions of institutional leadership share significant responsibility. Institutional leaders should ensure there is an environment that enhances research integrity and provide proper training and oversight. When there are indications of violations of research integrity, whether arising inadvertently or through misconduct, the institutional leadership must respond quickly and appropriately. In settings where there have been substantial failures in oversight by institutional leadership, the Office of Research Integrity should require that there is a transparent investigative process that ensures accountability, not only for the individuals involved in the research but also for those in institutional leadership positions who have oversight responsibilities.

A far less recent, but widely publicized misdeed occurred at another institution when a fellow in cardiology fabricated data[4]. The investigation was notable in several respects including the accidental nature of the initial discovery as well as his dismissal and public apology coupled with a 10-year moratorium on conducting federally funded research. Most remarkable, however, was the discovery that his fabrication had occurred over a 14-year period that included, at least one other academic institution. These discoveries led to 30 manuscripts being retracted from one institution and 52 from the other. At that time, it

became apparent that these fabrications managed to evade three safeguards. The first is peer review, in which experts advise funding agencies, especially the federal government, about which scientific proposals should be funded. The second is the referee system, in which scientific journals send manuscripts to anonymous peer reviewers to judge their merit for publication. The final safeguard is replication, in which independent scientists at other research institutions repeat the experiments. All of these impediments to fabrication need adequate surveillance by institutions.

Emerging Needs and Priorities for Academic Institutions

With respect to avoidance of these unfortunate circumstances that inflict great harm to the public, academic institutions, and the overwhelming majority of researchers who strive for scientific excellence and integrity, we believe one overarching problem is a lack of institutional and faculty awareness of compliance requirements with existing research regulations. These circumstances create a cascade of issues that also affect the staff, students, and the safety of research participants. These issues are further compounded by a lack of centralized monitoring and adequate enforcement.

All academic institutions should be willing to leverage their available resources to achieve and maintain research integrity[5]. These issues encompass identification of the best bench marking practices, establishment of a research compliance infrastructure and the implementation of a quality assurance plan. These priorities should include the assessment of research climate, development of policies and responsibilities for ethics investigations, and a process for resolution of formal disputes. This will foster consistency and exchange of information throughout the academic community. In addition, establishing lists of independent experts to conduct periodic reviews of institutional procedures may be helpful. Possible suggestions for improvements include evaluating the current research environment using validated tools such as the widely used and validated Survey of Organizational Research Climate, reinforcing existing regulatory policies that include emails regarding grant routing and regulatory policies, and providing both formal and informal training to faculty, staff, and trainees. In addition, there should be communication through these and other avenues of all significant new or revised United States Public Health Service and National Science Foundation regulations, which reinforce existing guidelines and address new and emerging issues.

With respect to accountability of principal investigators, concerns revolve around lack of awareness or understanding of regulatory policies, inadequate training, poor mentorship, and lack of adequate oversight of staff and students. We propose several suggestions for risk mitigation strategies, which include reminders of principal investigator expectations and accountability, rewarding compliance and incentivizing quality improvement, implementing software tools that enforce as well as reinforce requirements, and providing individual mentorship, as necessary.

The issues surrounding faculty and trainees generally arise from insufficient oversight and training as well as inadequate mentorship. We suggest possible risk mitigation strategies that include implementation of formal transparent agreements between mentors and mentees, and maintaining compliance through institutional and national training programs such as the

Collaborative Institutional Research Initiative program. This suggestion includes ensuring automatic tracking of training completion and required renewals.

With respect to grant submissions, concerns include inaccuracies in submitted information, incomplete research portfolios, and non-compliance with the institutional timelines. In these regards, risk mitigation strategies include more effective communication and enforcement of grant submission guidelines as well as adoption of routing forms to better communicate and enforce regulatory expectations. In addition, it is important to utilize *ad hoc* external review committees to conduct merit reviews with the goal of achieving strict compliance with all federal and other requirements.

Achieving research integrity also demands strict attention to the adequate protection of human subjects. This concern may include risks to research subjects, including students, if there are violations with respect to institutional review boards and individual privacy as protected by Family Educational Rights and Privacy Act and the Health Insurance Portability and Accountability Act. The mitigation of these concerns will derive from greater education and more effective institutional oversight. The suggested measures include hiring and training knowledgeable, competent personnel and working to support and train members of Institutional Review Boards, Environmental Health and Safety Boards as well as Office of Research Integrity.

The Offices of Research Integrity also play crucial roles in identifying and managing conflicts of interest for their researchers. Conflicts of interest may be financial or intellectual and also may occur among reviewers or even editors of journals. Public trust in the peer review process and the credibility of published articles begins at the each individual institution and their Offices of Research Integrity to elicit proper disclosure by researchers and proper management plans that include oversight, data collection, analysis and interpretation before a research grant is funded. Management of conflicts of interest will also encompass manuscript preparation, peer review and editorial decision-making. In this regard, the Committee on Publication Ethics requires signed statements from all authors that either declares no conflicts of interest or discloses them. Recently, at another institution, a researcher failed to disclose receipt of over $3 million dollars from drug and device companies. Of relevance, the Physician Payments Sunshine Act, a 2011 law, states that medical researchers have no right to privacy over payments made to them by drug companies.

Other financial improprieties range from under budgeting, failure to invoice, and questionable billing procedures. We suggest that mitigation strategies include billing and research compliance processes as well as involving legal and insurance professionals.

Summary and Conclusions

To achieve and maintain public trust, medical researchers must achieve and maintain research integrity. To do so requires synchronicity and collaboration between, as well as within, all academic institutions[6]. Substantial failures to maintain research integrity by institutional leadership will appropriately lead to increasing demands to do so from the funding organizations as well as the general public. This, in turn, will lead to avoidable

consequences of substantial penalties, financial and otherwise, adverse publicity and reputational damage.

Researchers must self-regulate to avoid pitfalls, including those created by changes in the medical care delivery system that have decreased the influence of health care providers and increased the influence of outside legal and business interests. Our common goal should be to return public trust in our research enterprise that has done so much good for so many, but requires the establishment and maintenance of vigilance to establish and maintain research integrity. . .

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Professor DeMets also reports that that he is a consultant to the National Institutes of Health, the Food and Drug Administration and the pharmaceutical and medical device industry on the design, monitoring and analyses of randomized trials. He receives compensation for serving on several industry sponsored data monitoring committees including Astra Zeneca, Amgen, Action, GSK, Merck, Sanofi, Boehringer Ingelheim, Teva & Abbvie. He holds no stock in any pharmaceutical or device company.

Dean Wood also reports that she serves as an independent scientist in an advisory role to investigators and sponsors as a Member of two Data Monitoring Committees for Amgen.

Professor Hennekens also reports that he serves as an independent scientist in an advisory role to investigators and sponsors as Chair or Member of Data Monitoring Committees for Amgen, British Heart Foundation, Cadila, Canadian Institutes of Health Research, DalCor, and Regeneron; to the United States Food and Drug Administration, and UpToDate; receives royalties for authorship or editorship of 3 textbooks and as co-inventor on patents for inflammatory markers and cardiovascular disease that are held by Brigham and Women's Hospital; has an investment management relationship with the West-Bacon Group within SunTrust Investment Services, which has discretionary investment authority; does not own any common or preferred stock in any pharmaceutical or medical device company.

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Clinical Significance

- Clinicians rely on integrity of researchers in reading and interpreting the medical literature and guidelines
- Integrity and trust are essential attributes of medical researchers.
- Research misconduct represents clear and present dangers to academic institutions and practicing clinicians
- We review the means to achieve and maintain research integrity
- We must restore public trust in the research establishment that has done so much good for so many.