

A Tale of Two Perspectives: Regulation Versus Self-Regulation. A Financial Reporting Approach (from Sarbanes–Oxley) for Research Ethics

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Abstract Reports of research fraud have raised concerns about research integrity similar to concerns raised about financial accounting fraud. We propose a departure from self-regulation in that researchers adopt the financial accounting approach in establishing trust through an external validation process, in addition to the reporting entities and the regulatory agencies. The general conceptual framework for reviewing financial reports, utilizes external auditors who are certified and objective in using established standards to provide an opinion on the financial reports. These standards have become both broader in scope and increasingly specific as to what information is reported and the methodologies to be employed. We believe that the financial reporting overhaul encompassed in the US Sarbanes–Oxley Act of 2002, which aims at preventing accounting fraud, can be applied to scientific research in 4 ways. First, Sarbanes–Oxley requires corporations to have a complete set of internal accounting controls. Research organizations should use appropriate sampling techniques and audit research projects for conformity with the initial research protocols. Second, corporations are required to have the chief financial officer certify the accuracy of their financial statements. In a similar way, each research organization should have their vice-president of research (or equivalent) certify the research integrity of their research activities. In contrast, the primary responsibility of the existing Research Integrity Officers is to handle allegations of research

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misconduct, an after-the-fact activity. Third, generally accepted auditing standards specify the appropriate procedures for external review of a corporation's financial statements. For similar reasons, the research review process would also require corresponding external auditing standards. Finally, these new requirements would be implemented in stages, with the largest 14 research organizations that receive 25% of the total National Institutes of Health funding, adopting these research oversight enhancements first.

Keywords Accounting · Disclosure · Financial audit · Mandatory reporting · Research ethics · Sarbanes–Oxley · Scientific misconduct · Trust · Publishing standards · Professional autonomy

Introduction/Background

It is instructive to examine how the US has attempted (after the Enron fraud) to prevent future deceptive accounting practices through increased regulation as specified by the Sarbanes–Oxley Act (SOX) (Rezaee 2007). This approach of regulation for accounting reports differs from the approach of self-regulation for scientific research ethics. There is no systematic regulatory oversight of research ethics by either the National Institutes of Health (NIH) or the National Science Foundation (NSF). Only Food and Drug Administration audits have specific evaluation standards. The only research integrity requirement for research facilities is to document the existence of a Responsible Conduct of Research (RCR) program.

We propose that research ethics, like corporate ethics, would be enhanced by increased oversight. We propose a departure from self-regulation, unquestioned reassurances and self-reports. Others have also proposed using outside evaluators to enhance research integrity (Titus and Bosch 2010). Researchers should adopt the financial accounting approach in establishing trust through an external validation process, in addition to the reporting entities and the regulatory agencies.

Additional regulations are unlikely to be welcomed by either the researchers or their institutions. However, there are no viable alternatives. The approach of increasing oversight and regulation has been consistently pursued for strengthening the integrity of accounting reports (Brenkert 2004). Alternative approaches have not been perceived as realistic or effective. In the current environment of increasing transparency and accountability to taxpayers and funding agencies, the increased regulation of research ethics is not an option. Just as increased federal regulations were used to strengthen accounting reporting ethics with SOX, a similar approach would be appropriate for research ethics. Any regulation of research ethics would depend upon the requirements of the primary funding agencies, NIH and NSF. The concentration of research funding among a small number of research institutions, makes it feasible to review major portions of the total research budget with focused efforts.

The general conceptual framework for reviewing financial reports, utilizes external auditors who are certified and objective in using established standards to provide an opinion on the financial reports. These financial reporting standards, over

the course of time, have resulted in increasing disclosure both through the increased scope and increased specificity as to what information is reported and the methodologies to be employed.

The general trend of increased scope and specificity in financial reporting standards is a response to changes in the general business environment and business fraud, and failures in past reporting practices. The Sarbanes–Oxley Act (SOX) is the most recent American federal legislation affecting financial reporting that has transformed a range of business behaviors that were previously nebulously defined and classified as ethically desirable, into specific legal requirements. These regulatory changes were implemented in recognition of perceived deficiencies in reporting and potential conflicts of interest among the auditors. The purpose of SOX was to prevent the failures (deception) in financial reporting that occurred in the cases of Enron and Worldcom.

Financial reports must be audited for all publicly traded companies. This is an extensive external review process that occurs regardless of any documented or suspected deficiencies. This is in addition to reviews by the reporting company and the regulatory agencies.

There is no equivalent regulatory oversight process for research integrity at either the institutional or research project level. There are few regulations, no systematized evaluations and no integrated assessments of research integrity. The major requirement is to establish a Responsible Conduct of Research program. These deficiencies in regulation and oversight limit the detection and correction of research integrity problems.

Others have proposed additional oversight through special institutional inspections which would allow access to additional funding (Titus and Bosch 2010). Educational (Steneck 2007) and judicial approaches (Downie 2006) have been proposed to enhance research integrity. In this paper we propose an accounting approach based on the Sarbanes–Oxley Act (Brenkert 2004).

Trust is a fundamental requirement in both the research and financial communities (Titus et al. 2008; Rezaee 2007). In the research community, a number of high-profile incidents have raised serious concerns about research integrity over the past few years (Errami and Garner 2008). Research misconduct wastes resources, misleads colleagues and destroys trust in science and support for public funding.

Proposals to establish trust in science and engineering research have been fragmented, with no overriding systematic conceptual framework. Financial reporting has a long history of dealing with crises of confidence (Clikeman 2008). We propose that science and engineering research consider the integrated systems developed to establish trust in financial reporting.

Our proposals draw on the latest US legislative response to the financial crisis of 2002, the Sarbanes–Oxley Act (SOX) (Wikipedia 2010). The accounting framework is the result of a long history of reacting to lack of trust in the financial markets. The Sarbanes–Oxley Act of 2002 enhanced standards for boards of directors, management and public accounting firms.

Sarbanes–Oxley Act: Internal Controls

First, SOX requires corporations to have and document a complete set of internal controls, to ensure the validity of their financial reports. For similar reasons, the bigger research organizations should document and retain the processes, analytic procedures and methodologies for each research project and maintain internal depositories for all relevant data. In scientific and engineering research projects, it is not rare for basic data results and analyses to be scattered or inaccessible. We are proposing the establishment of a formalized process to collect and retain project data and results in a centralized location. The complexities and costs of long-term of storage of research materials has already been recognized (John 2009; Lynch 2008). These materials could be sampled by internal and external oversight bodies. Similar specific rules are needed for lab procedures, analytic methods and the internal review process. This is a critical component in the process of enhancing trust.

Currently, institutions do not generally monitor research projects, particularly the non-financial aspects, on an ongoing basis.

Relevant information must be reported in a timely manner. In the case of scientific and engineering research, most projects disclose information at three points of time, application for funding, submission for publication and publication. We propose that research organizations publish research oversight reports for individual projects at a point after the application for funding, but before submission for publication.

We are proposing not only the collection of data and documentation by project, but the ongoing audit of those project reports. So, just as only a statistical sampling of the transactions affecting the important or vulnerable components of the financial statements are audited, only a sample of the research project documents would be reviewed.

The institution of record is primarily responsible for the enforcement of ethical standards (Editorial 2010). Other entities, such as the academic journals, professional associations and funding agencies have limited power to penalize misconduct.

For clinical trials of new medications on human subjects the sponsoring drug company and the Food and Drug Agency conduct audits of clinical trials (Mihajlovic-Madzarevic 2010). We are proposing that the institution where the research project physically occurs, should also conduct ongoing internal reviews.

A short example, of what the reviews for clinical trials currently include, follows. First, the files for a selection of recently recruited subjects are audited for consistency with the specified recruitment criteria. Second, the randomization of treatments are reviewed. Third, the informed consent forms are verified for accuracy, compliance with the Institutional Review Board (IRB) approval and completeness. Fourth, the documentation of medical care provided is checked for completeness and consistency with treatment protocols. Fifth, the reasons for, and characteristics of, patient withdrawals are reviewed. The data collected are compared with the original protocol. The analyses of data are similarly compared to those specified in the application. Finally, the storage of patient records is verified (Mihajlovic-Madzarevic 2010).

In addition there should be documentation specifying the co-authors' roles in the research project and manuscript creation, and where reports of the research were submitted and published. This ongoing process of monitoring the non-financial and ethical aspects of research projects internally should result in fewer instances of institutions learning of inappropriate activities through third parties.

Sarbanes–Oxley Act: Certification by Chief Financial Officer

Second, SOX specified that the Chief Financial Officer personally certifies that s/he understands the methods used to create the financial reports. Although s/he does not personally check the accuracy of financial statement numbers, s/he affirm that there are systems in place to detect reporting improprieties. In a similar way, we propose that the bigger research organizations should have their Vice-President of Research (or equivalent) certify their responsibility for research integrity.

Currently, institutions receiving funding from the US Public Health Service are required to appoint a Research Integrity Officer (RIO). The role of the RIO is very limited compared to the responsibilities we propose. The RIO's role is after the fact,—primarily concerned with handling allegations of misconduct (Michigan State University 2009). In contrast, our proposal is proactive, concerned with prevention, ensuring the collection of relevant non-financial information and that ongoing reviews of research projects take place.

Sarbanes–Oxley Act: External Audits

Third, SOX increased regulations for required external audits of corporations. The purpose of external audits is to reduce fraud. We propose a similar external review process for the research projects at the bigger institutions. As occurs in financial audits, sampling of information would occur.

Standard research oversight processes are difficult to establish. We, therefore, propose the creation of an external body for establishing standards and procedures for reviewing research projects and the accreditation of individuals and organizations to perform those reviews. This could eventually result in a set of international ISO standards.

Sarbanes–Oxley Act: Proposed Implementation in Stages

Finally, we are proposing the Sarbanes–Oxley approach for the bigger research institutions initially. Our review proposals could be phased in. In the case of National Institutes of Health (National Institutes of Health 2010) funding, there were 14 institutions receiving 25% of total NIH funding, then an additional 28 institutions with the next 25% of funding and next to the 53 institutions receiving the third quartile of funding. Although the review would not apply, at first, to the remaining organizations (each with under \$55 million of annual NIH funding), there

would still be one standard for research review. In the case of National Science Foundation (NSF) funding during 2008 (Ross 2008), there were 16 institutions receiving 25% of total NSF funding and 34 institutions receiving the next 25%. These institutions each received at least \$30.8 million.

Our proposals on research integrity have been drawn from accounting. Alternative frameworks exist. A judicial approach proposed the establishment of courts for adjudicating fraud (Downie 2006). The Sarbanes–Oxley approach is preventive.

Sarbanes–Oxley procedures provide a framework for enhancing our existing systems for reducing ethical problems in the conduct of research.

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References

- Brenkert, G. G. (2004). *Corporate integrity and accountability*. Thousand Oaks, CA: Sage Publications.
- Clikeman, P. M. (2008). Called to account: Fourteen financial frauds that shaped the American accounting profession. Routledge.
- Downie, J. (2006). The Canadian agency for the oversight of research involving humans: A reform proposal. *Accountability in Research*, 13(1), 75–100.
- Editorial. (2010). Under suspicion. *Nature*, 464(7293), 1245.
- Errami, M., & Garner, H. (2008). A tale of two citations. *Nature*, 451, 397–399.
- John, J. L. (2009). The future of saving our past. *Nature*, 459, 775–776.
- Lynch, C. (2008). How do your data grow? *Nature*, 455, 28–29.
- Michigan State University (2009). Video: The role of the RIO. Office of research integrity, US Department of Health and Human Services. <http://ori.dhhs.gov/rio/riovideo/>. Accessed 26 June 2010.
- Mihajlovic-Madzarevic, V. (2010). *Clinical trials audit preparation: A guide for good clinical practice (GCP) inspections*. Hoboken, NJ: Wiley.
- National Institutes of Health (2010). Award data 2006 (aggregate data for individual organizations). Research Portfolio Online Reporting Tools (RePORT), Reports, Data and Analyses of NIH Research Activities. <http://report.nih.gov/award/trends/AggregateData.cfm?Year=2006#skipnav> Accessed 5 July 2010.
- Rezaee, Z. (2007). *Corporate governance post-Sarbanes-Oxley: Regulations, requirements, and integrated processes*. Hoboken, NJ: Wiley.
- Ross, V. (2008). Budget internet information system: Providing statistical and funding information. Budget Division, Office of Budget, Finance and Award Management, National Science Foundation. <http://dellweb.bfa.nsf.gov/>. Accessed 27 June 2010.
- Steneck, N. H. (2007). *ORI introduction to the responsible conduct of research*. Washington, DC: US Department of Health and Human Services.
- Titus, S. L., & Bosch, X. (2010). Tie funding to research integrity. *Nature*, 466, 436–437.
- Titus, S. L., Wells, J. A., & Rhoades, L. J. (2008). Repairing research integrity. *Nature*, 453, 980–982.
- Wikipedia (2010). Sarbanes-Oxley Act. Wikipedia, the free encyclopedia. <http://en.wikipedia.org/wiki/Sarbanes-Oxley>. Accessed 26 June 2010.

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