

Research Compliance Professional's Handbook, Third Edition

3 Scientific and Research Misconduct

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Scientific and research misconduct may present the most vexing of challenges for the compliance officer. Lines of inquiry that have been supported by human and animal subjects (and sacrifice), as well as significant financial investment, can be wholly discredited and rendered worthless if misconduct has occurred. Careers may be ruined and institutions shamed. Settlements, fines and awards deplete resources and imprisonment may await those who would perpetrate fraud upon the government. Investigators may be excluded from participating in Public Health Service (including National Institutes of Health) and National Science Foundation supported research. In addition, private causes of action from defamation to conversion (theft) may be available to victims.

Most areas of compliance address developing an institution-wide approach to ensuring that behaviors, practices and systems are consistent with laws and regulations. If an electronic medical record has been improperly accessed, providers have programs that will detect such a breach. The fact of the breach and its electronic detection does not have a personality. Conversely, allegations of scientific or research misconduct may arise among colleagues who work together or out of a position of trust (peer review of grant proposals; work overseen by a dissertation advisor). The real or apparent violation takes on a life of its own as those who used to go about their business in peaceful co-existence take sides and prepare for battle. Institutional anxiety runs high as those not directly involved seek to avoid the fall-out.

This chapter will review governing regulations and provide examples of scientific misconduct. A distinction is drawn between scientific misconduct and regulatory misconduct. The latter is conduct inconsistent with regulations and standards that govern the process of research, and that are found, for example, in the Common Rule, the Health Insurance Portability and Accountability Act (HIPAA), and regulations regarding the use of animals. Scientific misconduct may, indeed, include elements of some or all of these, and can be found in other sections of this compendium; however, this chapter will focus on the standards enunciated in 42 C.F.R. Part 93 (Department of Health and Human Services) and 45 C.F.R. Part 689 (National Science Foundation) that address institutional responsibilities regarding “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.” The essence of this chapter and its body of rules is to support the integrity of the public investment in “biomedical and behavioral research, research training or activities related to that research ...”^[2] It should be noted that compliance with the section is required upon application for support and is not contingent upon success in securing funding.

Institutions that seek Public Health Service (PHS) funding are required to have in place an “assurance.” This assurance certifies that the institution has adopted and implemented policies and procedures to address allegations of fabrication, falsification or plagiarism, including the identification of an appropriate institutional official to carry out the intent of such provisions, a research integrity officer (RIO). Prior to 1996, institutions filed an “initial assurance form;” however, beginning in 1996, signing the face page of a grant application constitutes/is deemed assurance. In addition, there is an annual reporting obligation that describes the status of activities that have taken place during the course of the preceding year. Failure to file a timely annual report could expose the institution to heightened scrutiny, as well as the need to pursue reinstatement of its assurance status

in order to become eligible for Public Health Service (PHS) funding.

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