

Dealing With Charges of Scientific Misconduct

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A leading AIDS researcher at a major university receives a letter from a well-known investigative reporter. The letter questions the academic credentials of a member of the researcher's team. It further claims that the team member has falsified results of a study of what appeared to be a promising new AIDS drug. Finally, it asks for a response within ten days and states that, in the absence of a response, the reporter will "assume" that the allegations are true.

What should be done? Should the researcher confront the individual about whom the allegations have been made and directly ask if the allegations are true? Should the researcher report the letter to the Dean or the Faculty Senate? Should the university immediately launch an internal investigation? If the research is federally funded, should the university notify the sponsoring agency? Should anyone at the university make direct contact with the reporter?

The need to face such perplexing questions has become increasingly common in the academic community. Just this February, the Baylor College of Medicine settled a \$25 million lawsuit brought against it by a university researcher who had been fired for allegedly falsifying research results. The cases of Dr. Bernard Fisher of the University of Pittsburgh and Dr. David Baltimore of Rockefeller University, both of whom were accused of "scientific misconduct" (and later entirely exonerated), have been highly publicized. Other, less visible cases have vexed university administrators and led to contentious proceedings before the Department of Health and Human Services, which oversees most federally-funded bio-medical and behavioral research.

How universities respond can have significant and, in some cases, devastating consequences. Academic careers can be materially damaged, if not destroyed. University presidents can be called upon the carpet by Congressional oversight committees, forced to grovel before their elected representatives and find their management practices excoriated in the public press. Faculty members sitting on review panels may be sued, as in Baylor Medical College case, and, at least under some theories, might conceivably end up personally liable to a sanctioned or dismissed researcher. Government auditors may recommend that previously awarded grants be rescinded and that monies already expended be reimbursed to the federal government. Individual researchers and even entire institutions may find themselves "debarred" from competing for future federal grants.

Regulations of the Department of Health and Human Services, which are applicable to all institutions which apply for or receive financial assistance from the agency under grant or cooperative agreement, require that grantees have standards and procedures in place for dealing with allegations of "scientific misconduct". Under these regulations, universities have defined scientific misconduct and generally established procedures which provide for a two-step review of allegations of misconduct: first, an informal "inquiry", and, second, a more formal "investigation".

Although detailed procedures generally exist on paper, nonetheless their application in practice is often murky. Strictures on maintenance of confidentiality are not absolute and are frequently violated. The HHS Office of Research Integrity investigation of Dr. Bernard Fisher, for example, was widely reported in the press. Formal "dockets" may not be maintained, at least at early stages of the proceedings, and interviews of witnesses may not be transcribed or recorded. Even though procedures generally allow the accused individual to be assisted by counsel, the role of attorneys is unclear. Some committees may permit attorneys to question witnesses; others may not. There are few, if any, safeguards against innuendo and unsupported, malicious gossip entering the record and permanently staining a researcher's reputation.

In the collegial setting of a university campus, moreover, "due process" may be regarded as unnecessary or a nuisance. An adversarial setting may make the researcher accused of misconduct extraordinarily uncomfortable. This is especially so where an investigating committee may consist of fellow scientists with whom the accused researcher may be personally collaborating with in the future.

Where does this leave our hypothetical researcher in receipt of the letter from the investigative reporter? Simply to ignore it may be perilous, particularly if it should later turn out that there is some truth to the allegations. Personally questioning the accused scientist could lead to later charges of a cover-up, or at least investigative incompetence, if the allegations are not pursued further. Responding directly to the reporter is almost never likely to be productive: answering one question will lead to ten more, and, if at some point an effort is made to cut short the dialogue, the reporter will only draw negative inferences from the failure to answer subsequent inquiries.

From a procedural perspective, the most prudent course of action is to turn the letter over to the responsible administrative officer within the university. Indeed, this is often required under university procedures. The HHS regulations appear to leave relatively little discretion, mandating that grantees "[t]ake immediate and appropriate action as soon as misconduct ... is suspected or alleged." Making such a referral, in any case, protects the researcher – and the university – against charges of cronyism and ensures that an "objective" review of the allegations will be made.

Once notified, the university official must then decide which allegations fall within the university's standards of misconduct and which do not. For example, allegations, however egregious, relating to the extramural activities of a scientist or otherwise not relating to the conduct of scientific research, may be outside the scope of legitimate university inquiry. Charges must then be defined, consistent with applicable HHS and university standards, in order to put the accused scientist on proper notice.

The initial stages of internal review, needless to say, are of critical importance. Because the entire review is confidential, it would be inappropriate in any way to respond to the reporter's inquiries while the review is in process, or even to advise the reporter of the existence of such a review. At the same time, as noted earlier, under HHS regulations there is no requirement to report the allegations to ORI until a formal investigation is commenced. Consequently, the matter can be handled entirely in-house. It must, of course, be handled with strict impartiality and include a thorough and objective, albeit preliminary, review of available evidence.

During the initial phase, the responsible administrative officer may or may not appoint an inquiry panel. Except in the case of patently frivolous or untrustworthy allegations, however, doing so further insulates the university against charges that it cannot or will not police its own house. Furthermore, creation of an inquiry panel ensures that, at least in the case of HHS-funded research, HHS cannot complain that federally-mandated review procedures, which call for an "inquiry" whenever there is "an allegation or other evidence of possible misconduct," are being ignored.

In most cases, an inquiry should be sufficient to establish whether a scientific misconduct charge can be sustained or not. Whether an academic has misrepresented his or her credentials, for example, can usually be readily established on the basis of indisputable documentary evidence, e.g., an individual either holds particular degrees or doesn't. During the inquiry, the scientist should be interviewed and given a chance to respond to charges, and his or her explanation can also frequently be sufficient to bring the inquiry to a close. The investigatory stage should be reserved for cases where there is "probable cause", based upon reliable evidence, that a violation of the university standards has occurred, but where there is not sufficient evidence to make a definitive finding, either because the facts are contested or because there is a need for further fact gathering. In this way, the pursuit of scientific misconduct allegations can be contained yet dealt with in a responsible fashion.

Finally, if an investigation is deemed appropriate, the university must be diligent in protecting the rights of the individual accused of scientific misconduct. This means, among other matters, clearly specifying the charges and their basis; maintaining confidentiality; transcribing or recording all interviews and making them available to the accused scientist and his or her counsel; ensuring that all written submissions, documentary evidence, interview transcripts, and the like are adequately docketed, filed and available for inspection; and providing reasonable opportunity for counsel to examine adverse witnesses before the investigating committee. While the "judicialization" of internal university processes may seem unduly

legalistic, unpleasant and/or even repugnant to some, there is no easy substitute for securing a result that will be deemed both inside and outside the university community to be "fair" to all concerned.

In sum, the touchstones for dealing with the investigative reporter's letter must be adherence to established procedure and reliance on an impartial process to determine the validity of the allegations in light of the university's standards for the conduct scientific research. When the queried researcher – and the research institution – respond in this fashion, the integrity of both can and should be considered above reproach.