association of american
medical colleges

The Maintenance Of High Ethical Standards In The Conduct Of Research

Suite 200, One Dupont Circle, N.W., Washington, D.C. 20036

AAMC Ad Hoc Committee on the Maintenance of High Ethical Standards in the Conduct of Research

JULIUS R. KREVANS, M.D., *Chairman*, Dean, University of California, San Francisco, School of Medicine

JAMES W. BARTLETT, M.D., Medical Director and Associate Dean for Clinical Affairs, University of Rochester, School of Medicine and Dentistry

STUART BONDURANT, M.D., Dean, University of North Carolina at Chapel Hill School of Medicine

DAVID BROWN, M.D., Professor, Department of Laboratory Medicine/Pathology/Pediatrics, University of Minnesota Medical School

NATHAN HERSHEY, Professor of Health Law, University of Pittsburgh, Graduate School of Public Health

ROBERT HILL, Ph.D., Chairman, Department of Biochemistry, Duke University Medical Center

HAROLD HINES, President, Ryan Insurance Group

ARNOLD S. RELMAN, M.D., Editor, *New England Journal of Medicine*

JEFFREY SKLAR, M.D., Ph.D., Assistant Professor of Pathology, Department of Pathology, Stanford University School of Medicine

LEROY WALTERS, Ph.D., Director, Center for Bioethics, Kennedy Institute, Georgetown University

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Foreword

In January 1982, the Association of American Medical Colleges appointed an *Ad Hoc* Committee on the Maintenance of High Ethical Standards in the Conduct of Research. The committee was chaired by Julius R. Krevans, M.D., Dean of the University of California, San Francisco. The decision to establish this committee resulted from concerns that the wide attention received by several instances of misconduct by biomedical investigators would call into question the integrity of the whole research enterprise.

The Association believes that faculties and their institutions have the primary responsibility to maintain high ethical standards in research and to investigate promptly and fairly when misconduct is alleged.

The committee report was adopted by the Executive Council on June 24, 1982, as a guide to faculties of the medical schools and teaching hospitals who are responsible for the integrity of the biomedical research enterprise.

John A.D. Cooper, M.D.
President
Association of American Medical Colleges

Introduction

The principles that govern scientific research have long been established and have been applied by faculties and administrators of academic medical centers and teaching hospitals for the discovery of the new knowledge that is needed to promote the health and welfare of mankind. The maintenance of high ethical standards in research based on these principles is a central and critical responsibility of faculties and administrators of academic medical centers. Recently, however, there have been a number of instances of misconduct, including fraud, in research and in reporting of research data which have received wide attention. Validity and accuracy in the collection and reporting of data are intrinsically essential to the scientific process; dishonesty in these endeavors runs counter to the very nature of research, that is, the pursuit of truth.

The responsibility of the scientific community to the public is acknowledged. The maintenance of public trust in this pursuit is vital to the continuing vigor of the biomedical research enterprise. Loss of this trust because of isolated instances of dishonest behavior on the part of a few researchers could cause great harm by calling into question in the mind of the public the validity of all new knowledge and the integrity of the scientific community at large. In short, it is in the best interest of the public and of academic medicine to prevent misconduct in research and to deal effectively and responsibly with instances where misconduct is suspected.

The primary goal of this document is to set forth guidelines and recommendations that will be useful to medical schools and teaching hospitals in designing their individual institutional approaches to dealing with alleged misconduct by researchers. Although the guidelines and recommendations that follow principally address fraud (i.e., the intentional fabrication, falsification, or "stealing" of research data) they may also be useful in institutional efforts to deal with the violation of existing administrative procedures and ethical codes for the treatment of human and animal subjects of research and other problems that may arise in the conduct of research.

The Prevention of Research Fraud

The primary responsibility for taking steps to prevent research fraud rests with the scientific community. In academic institutions, it can best be executed by the faculties. In a free society, and particularly in the academic milieu where creativity and individual thought are qualities to be fostered and not stifled, aberrant behavior of individuals cannot be completely controlled. It is unrealistic, therefore, to assume that research fraud can be entirely prevented. On the other hand, faculties can create a climate that promotes faithful attention to high ethical standards. This climate should enhance the research process and should not inhibit the productivity and creativity of scientists.

It is recognized that the principal deterrent in research fraud is the overwhelming probability that fraudulent data will be detected soon after their presentation. Virtually all experimentation leading to scientific findings of significance will be repeated, and the likelihood that falsified, fabricated, or plagiarized data will go unquestioned is exceedingly slim. Despite the self-correcting nature of science, however, instances of research fraud have occurred and faculties should explore additional measures to decrease further the likelihood that a researcher will risk the odds and commit fraud. Faculties and institutional officials should consider the following:

- Having in place a conspicuous and understandable mechanism for dealing with instances of alleged fraud.
- Adopting institutional policies that define misrepresentation of research data as a major breach of contract between the faculty or staff member and the institution. (This policy should particularly be articulated in the faculty handbook.)
- Articulating institutional policies that foster openness of research.
- Encouraging faculties to discuss research ethics to heighten awareness and recognition of these issues.
- Establishing institutional policies to provide: 1) an appropriate and clearly defined locus of responsibility for the conduct of research; 2) assurance that individuals charged

with supervision of other researchers can realistically execute their responsibility; and 3) particular attention to adequate supervision of large research teams.

- Assuring that quality rather than quantity of research is emphasized as a criterion for the promotion of faculty.

- Examining institutional policies on authorship of papers and abstracts to ensure that named authors have had a genuine role in the research and accept responsibility for the quality of the work being reported.

- Reviewing institutional policies on the recording and retention of research data to ensure that such policies are appropriate and are clearly understood and complied with by all faculty.

- Examining the institutional role and policies in guiding faculty concerning public announcement and publication of research findings.

Institutional Responses to Instances of Alleged Research Fraud

As previously stated, it is highly advisable for faculties to have in place procedures to deal with reports of misconduct in order that alleged fraud can be investigated and resolved in an expeditious, thoughtful, fair, and judicious manner. Although it would be virtually impossible to anticipate in advance the precise course that all investigations and subsequent actions should take, procedures for handling initial reports of fraud should be established prospectively and all researchers should be cognizant of the existence of these procedures.

In developing policies and procedures, institutions and their faculties should recognize that judgments about the substantive questions relating to whether research findings are true or false must largely be made by faculty peers. If action adverse to a faculty member is taken by the institution based upon findings of fraud and such action is later challenged in court, the court ordinarily will look to see if fair procedures have been followed; that the accused had an adequate opportunity to explain and defend his actions, including when appropriate, confronting those

persons who presented evidence of fraud; and that the decision was not arbitrary or capricious, but based on credible evidence. If institutional policies and procedures meet these criteria the courts are unlikely to interfere with the institutional decision.

The following guidelines and procedures for dealing with allegations of fraud are offered as a prototype to assist schools in designing a process appropriate to their own situations. Consultations with university counsel in such an effort are strongly recommended. It is recognized that in these procedures a faculty member's reputation is put at risk during the investigation. This is justified since scientists on the university faculty occupy a special place of privilege and responsibility and must be held to a higher standard of conduct. The procedures indeed must be fair to the individuals involved. They must also be designed to be responsive to the special responsibility that science and faculty have to society.

Prototype of Procedures for Dealing with Alleged Research Fraud

A. Processing Initial Reports of Fraud

- From the outset, institutions should protect rights and reputations for all parties involved including the individual(s) who report perceived misconduct in good faith.

- Initial reports of alleged fraud should be brought to the attention of the faculty member responsible for the individual whose actions are in question. That person should in turn report the allegations to the department chairperson immediately.

- If the initial report of misconduct is not regarded as blatantly frivolous in nature, the report should promptly be referred to the dean or the chief executive officer of the institution. The dean should in turn immediately initiate a review by individuals at the institution who have been designated to review initial reports of fraud. Such individuals should be selected from among the faculty and administration. Care should be taken to exclude those with personal responsibility for the research under investigation.

- After this initial review, a determination should be made as to whether the report warrants more thorough investigation. If it is determined that there is sufficient basis for pursuing the allegations, the researcher(s) in question should be advised of the allegations and any collaborators should be informed of the pending investigation.

B. Investigation of Reported Fraud that Appears Substantial

- Institutions should have in place or be prepared to appoint immediately a committee or other administrative unit to conduct a prompt and thorough investigation of the reported fraud and should consider the merits of involving outside, objective parties in the investigation at this stage.

- The sponsoring agency should be notified that there is an investigation underway.

- During the investigation, consideration should be given to the review of all research with which the individual is involved.

- The investigating committee or unit should determine whether there was fabrication or dishonesty.

- Throughout the investigation, the individual and any collaborators or supervisors whose role in the alleged misconduct is questionable should be advised of the progress of the investigation and be afforded the opportunity to respond and provide additional information.

C. Subsequent Action Following Completed Investigation

1. If the alleged fraud is substantiated by a thorough investigation the following actions are recommended:

   - The sponsoring agency should be notified of the findings of the investigation and appropriate restitution should be made.

- All pending abstracts and papers emanating from the fraudulent research should be withdrawn and editors of journals in which previous abstracts and papers appeared should be notified.

- Institutions and sponsoring agencies with which the individual has been affiliated should be notified if there is reason to believe that the validity of previous research might be questionable.

- Appropriate action should be taken to terminate or alter the status of faculty members whose misconduct is substantiated.

- Institutional administrators should consider, in consultation with legal counsel, release of information about the incident to the public press, particularly when public funds were used in supporting the fraudulent research.

2. If the alleged fraud is not substantiated by a thorough investigation, formal efforts should be undertaken to restore fully the reputation of the researcher and others under investigation. In addition, appropriate action should be taken against any parties whose involvement in leveling unfounded charges was demonstrated to have been malicious or intentionally dishonest.

3. Subsequent to the completion of an investigation, faculty practices and institutional policies and procedures for promoting the ethical conduct of research and investigating allegations of misconduct should be scrutinized and modified in light of the experience gained.

Conclusion

The foregoing are offered as guidelines around which faculties and their institutions can develop processes for promoting ethical standards in research and in dealing with misconduct and fraud. It must be emphasized that developing an appropriate process for detecting and responding to alleged fraud is sensitive and

complex. Implementation of these policies and guidelines should not require the development of an elaborate, administrative bureaucracy. Simple, perfect, cut-and-dried procedures do not exist and to suggest that they do, ignores the difficulties inherent in achieving a balance between protecting the integrity of the research effort and protecting the rights of individuals.