APPENDIX X

POLICY FOR INTEGRITY AND THE RESPONSIBLE CONDUCT OF SCHOLARSHIP AND RESEARCH: GUIDELINES TO ENCOURAGE RESPONSIBLE RESEARCH PRACTICES

APPENDIX TO FACULTY BYLAWS

Policy for Integrity and the Responsible Conduct of Scholarship and Research: Guidelines to Encourage Responsible Research Practices.

Introduction

The community of scientists is bound by a set of values, traditions, and standards that embody honesty, integrity, objectivity, and collegiality. The diversity, flexibility, and creativity of the research community are strengths that have contributed to decades of scientific achievement and progress in the United States.

For centuries scientists have relied on each other, on the self-correcting mechanisms intrinsic to the nature of science and on the traditions of their community to safeguard the integrity of the research process. Recent and dramatic increase in the size and influence of the research enterprise, and in the amounts and patterns of funding, have led to changing social expectations about the accountability of scientists and their institutions for research supported by public funds. In addition, the changing nature of collaborative efforts, the quickening pace and increasing complexity of research endeavors, and the growing emphasis on commercialization of research results have combined to exacerbate stresses that have always been apparent to some extent in scientific research.

The self-regulatory system in science, which has evolved over the centuries to foster creativity and scientific achievement, may need to evolve further to meet the demands for public accountability that accompany government, foundation, and industrial support of scientific research. To respond to the need for more visible, explicit mechanisms to ensure integrity in the research process, and to handle allegations of misconduct in science, the following objectives should be addressed.

1. To develop vigorous approaches to protect and enhance knowledge of scientific traditions and sound research practices, and mechanisms to penalize those who engage in misconduct.

2. To foster responsible research conduct in a period of increasing diversification of funding sources, growing demands on limited research resources, and greater incentives for financial gain in the research environment.

3. To ensure fairness and balance in efforts to establish individual and institutional accountability in scientific research activities.

In concert with these objectives, the institution is obligated to protect and foster the academic freedom and intellectual integrity of all members of the institutions community in the pursuit of knowledge.

Scientists engaged in work involving human subjects should refer to the MSM IRB policy, and the "Code of federal regulations Title 45-Part 46-Protection of Human subjects".

A. Framework for Fostering Responsible Research Conduct

Integrity of the research process is defined as the adherence by scientists and their institutions to honest and verifiable methods in proposing, performing, evaluating, and

reporting research activities. Science is not only a body of information composed of current knowledge, theories, and observations, but also the process by which this body of knowledge is developed. Three categories of behaviors in the research environment warrant specific attention.

1. Misconduct in Science

   Fabrication, falsification, or plagiarism in proposing, performing, or reporting research. This does not include errors of judgment; errors in the recording, selection, or analysis of data; differences in opinions involving the interpretation of data; or misconduct unrelated to the research process. ***Fabrication*** is making up data or results, ***falsification*** is changing data or results, and ***plagiarism*** is using the ideas or words of another person without giving the appropriate credit.

2. Questionable Research Practices

   Actions that violate traditional values of the research enterprise and that may be detrimental to the research process.

   These do not directly damage the integrity of the research process, however, they can erode confidence in the integrity of the research process, violate traditions associated with science, affect scientific conclusions, waste time and resources, and weaken the education of new scientists.

Questionable research practices include:

- Failing to retain significant research data for a reasonable period
- Maintaining inadequate research records
- Conferring authorship for a contribution that is not significantly related to the research reported in the paper
- Refusing to give peers reasonable access to unique material or data
- Using inappropriate statistical analysis to enhance the significance of research findings
- Inadequately supervising research subordinates

3. Other Misconduct

   These practices include behavior which is clearly not unique to the conduct of science, i.e. sexual and other forms of harassment of individuals, misuse of funds, vandalism, including tampering with research experiments or instrumentation, and violations of government research regulations, such as those dealing with radioactive materials, recombinant DNA research, and the use of human or animal subjects.

Recommendations

As science becomes more closely linked to economic and political objectives, the processes by which scientists formulate and adhere to responsible research practices will be the subject of increasing public scrutiny. Scientists and research institutions thus need to clarify and strengthen the methods by which they foster responsible research practices. Ensuring the integrity of the research process requires that scientists and research institutions give systematic attention to the fundamental values, principles, and traditions that foster responsible research conduct. All who participate in the research enterprise share responsibility for the integrity of the research process. The following recommendations are aimed at strengthening the research enterprise, as well as

clarifying the nature of the responsibilities of scientists, research institutions, and government agencies in this area.

1. Scientists in cooperation with officials of research institutions should accept formal responsibility for ensuring the integrity of the research process. They should foster an environment, a reward system (i.e. when assessing promotion), and a training process that encourages responsible research practices.

2. Sabbatical programs that foster faculty and student awareness of concerns related to the integrity of the research process should be integrated into the current Sabbatical program.

3. Adoption of formal guidelines for the conduct of research. This should include a common framework of definitions, distinguishing among misconduct in science, questionable research practices, and other forms of misconduct.

4. Policies and procedures should be formulated to address other misconduct that may occur in the research environment such as theft, harassment, or vandalism.

B. Current Policies and Procedures at Morehouse School of Medicine

The Public Health Service implemented regulations (effective January 1, 1990) stating that any institution that applies for, or receives assistance under the Public Health Service Act, for any project or program which involves the conduct of biomedical or behavioral research, is required to complete and submit to the Office of Research Integrity (ORI) an assurance regarding procedures for dealing with and reporting possible misconduct in science. In compliance with Public Health Service regulations, MSM has adopted a document entitled, "Research Integrity Policy for Responding to Allegations of Scientific Misconduct" (See current MSM Bylaws of the Faculty). This policy was approved by the Academic Policy Council on July 1, 1983 and modified administratively on December 12, 1989, and in July, 2005 in order to comply with these regulations. The procedures outlined in this document are sufficient to handle reports of initial misconduct, however, MSM has not formulated a official framework for defining misconduct, nor has it established guidelines to encourage responsible research practices. To be effective, guidelines must be incorporated into the process of research and education and become an operational part of day-to-day activities. It would thus seem appropriate that if such policies should be formulated, they should be under the supervision of those who will be directly affected. We therefore set forth the following general principles to provide a common frame of reference. The following guidelines are proposed for defining misconduct.

1. Data Handling

Data handling refers to the acquisition, management, and storage of research results. Scientific experiments and measurements are typically transformed into research data. Research data are the basis for reporting discoveries and experimental results. When a scientist communicates a set of results and a related piece of theory or interpretation in any form, it is assumed that the research has been conducted as reported. It is a violation of the most fundamental aspect of the scientific research process to set forth measurements that have not, in fact, been performed (fabrication) or to ignore or change relevant data that contradict the reported findings (falsification).

On occasion what is actually proper research practice may be confused with misconduct in science. Responsible practice requires that scientists disclose the basis for omitting or modifying data in their analysis of research results, especially when such omissions or modifications could alter the interpretation or significance of their work.

Concerns about misconduct in science have raised questions about the roles of research investigators and of institutions in maintaining and providing access to primary data. Scientists are generally expected to exchange research data as well as unique research materials that are essential to the replication or extension of reported findings. However, it is well recognized that in the academic environment, centralized research records raise complex problems of ownership, control, and assess.

Recommendation on Data Handling

Research data, including the primary experimental results, should be retained for five years. Custody of all original primary laboratory data should be retained by the unit in which they are generated. All data, even from observations and experiments not leading directly to publication, should be treated in a likely manner. Research data should always be immediately available to scientific collaborators and supervisors for review.

C. Communication and Publication

In a publication, all data pertinent to the project should be reported, whether supportive or unsupportive of the thesis or conclusions. Except for review articles, publishing the same material in more than one paper should be avoided.

Plagiarism is using the ideas or words of another person without giving appropriate credit. Plagiarism includes the unacknowledged use of text and ideas from published work, as well as the misuse of privileged information obtained from peer review is not acceptable because the reviewer is in a privileged position.

Peer review is the process by which editors and journals seek to be advised by knowledgeable colleagues about the quality and suitability of a manuscript for publication in a journal. The proliferation of research journals and the rewards associated with publication and obtaining research grants have put substantial stress on the peer review system.

The reviewer has the responsibility for preserving the integrity of the review process. In reviewing a manuscript or a grant proposal, she or he is entrusted with privileged information that is unavailable to anyone outside of the laboratory of the submitting scientists. It is of obvious importance for the reviewer not to make use of information gained in the review for her or his own purposes until it is published or prior to that, only by consent of the author.

Recommendation on Communication & Publication

Authorship of original research reports is an important indicator of accomplishment, priority, and prestige within the scientific community. Authorship practices are guided by disciplinary traditions, customary practices within research groups, and professional and journal standards

and policies. A general rule is that an author must have participated sufficiently in the work to take responsibility for its content and vouch for its validity. Credit for authorship should be contingent on substantial participation in one or more of the following categories: 1) conception and design of the experiment, 2) execution of the experiment and collection and storage of the supporting data, 3) analysis and interpretation of the primary data, and 4) preparation and revision of the manuscript.

D. Correction of Errors

At some level, all scientific reports, even those that mark profound advances, contain errors of fact or interpretation. In part, such errors reflect uncertainties intrinsic to the research process itself--a hypothesis is formulated, an experimental test is devised and based on the interpretation of the results, the hypothesis is refined, revised, or discarded. Errors are an integral aspect of progress in attaining scientific knowledge.

Science is self correcting, and errors whether honest or products of misconduct, will be exposed in future experiments. Scientific truth is founded on the principal that results must be verifiable and reproducible. Publication of a scientific report provides an opportunity for the community at large to critique and build on the substance of the report, and serves as one stage at which errors and misinterpretations can be detected and corrected. The research endeavor can therefore be viewed as a two-tiered process: first, hypotheses are formulated, tested, and modified; second, results and conclusions are re-evaluated in the course of additional study.

Recommendation on Correction of Errors

In accordance with established principles of science, scientists have the responsibility to replicate and reconfirm their results as a normal part of the research process. The cycles of theoretical and methodological formulation, testing, and reevaluation, both within and between laboratories, produce an ongoing process of revision and refinement that corrects errors and strengthens the fabric of research.

E. Research Training, Supervision and Mentorship

A mentor, as a research advisor, is generally expected to supervise the work of the trainee and ensure that the trainee's research is completed in a sound, honest, and timely manner. The ideal mentor challenges the trainee, spurs the trainee to higher scientific achievement, and helps socialize the trainee into the community of scientists by demonstrating and discussing methods and practices that are not well understood. It is important to recognize that junior investigators may be particularly at risk in failing to distinguish, or prevent, unacceptable research practices.

Mentors should limit the number of trainees in their laboratory to the number for whom they can provide an appropriate research experience. Mentors should supervise the design of experiments and the processes of acquiring, recording, examining, interpreting and storing data.

The principles of science and the practices of the specific scientific disciplines are transmitted by scientists in classroom settings, and, perhaps more importantly in research groups and teams. The dynamics of research groups can foster or inhibit innovation, creativity, education, and collaboration. The laboratory director or group leader is the primary determinant of a group's practices. Individuals in positions of authority are visible

and are also influential in determining funding and other support for the career paths of their associates and students. Research directors and department chairs, by virtue of personal example, thus can reinforce, or weaken the power of disciplinary standards and scientific norms to affect research practices.

To the extent that the behavior of senior-scientists conforms with general expectations for appropriate scientific and disciplinary practices, the research system is coherent and mutually reinforcing. Thus, personal example and the perceived behavior of role models and leaders in the research community can be powerful stimuli in shaping the research practices of colleagues, associates, and students.

Recently, the demands of obtaining sufficient resources to maintain a laboratory in the contemporary research environment often separate faculty from their trainees. When laboratory heads fail to participate in the everyday workings of the laboratory, their inattention may harm their trainees education. In addition, problems arise when faculty members are not directly rewarded for their graduate teaching or training skills. When institutional policies fail to recognize and reward the value of good teaching and mentorship, the pressures to maintain stable funding for research teams in a competitive environment can overwhelm the time allocated to teaching and mentorship by an investigator.

Research supervisors must devote attention to maintaining an atmosphere of open communication and cooperation in their research groups, with opportunity for appropriate participation by and recognition of all parties. Considering human relationships and interactions is an important aspect of good research practice.

Recommendation on Research Training, Supervision and Mentorship

Research mentors, laboratory directors, department heads, and senior faculty are responsible for defining, explaining, exemplifying, and requiring adherence to the value systems of their institutions. A mentor is defined as that person directly responsible for the professional development of a research trainee. Professional development includes both technical training and socialization in basic research practices (i.e. authorship practices and sharing of research data). The mentor has the responsibility to supervise the trainee's progress closely and to interact personally with the trainee on a regular basis in such a way as to make the training experience a meaningful one. The neglect of sound training in a mentor's laboratory will over time compromise the integrity of the research process.

F. Conclusions

The self-regulatory system that characterizes the research process has evolved from a diverse set of principles, traditions, standards, and customs transmitted from senior scientists, research directors, and department chairs to younger scientists by example, discussion, and informal education. The principles of honesty, collegiality, respect for others, and commitment to dissemination, critical evaluation, and rigorous training are characteristic of all the sciences.

Guidelines for the conduct of research differ from institutional policies that are designed to address misconduct in science, conflict of interest, or that have been formulated in response to regulatory requirements governing research involving human subjects, hazardous materials, or recombinant DNA. Research conduct guidelines are intended to promote responsible conduct of research and, to the extent that questionable practices and misconduct in science are linked, to reduce the amount of misconduct in science.

Administrative officials within the research institution bear responsibility for ensuring that good scientific practices are observed in units of appropriate jurisdiction. In addition, they should balance reward systems appropriately to recognize research quality, integrity, teaching, and mentorship. Adherence to scientific principles and disciplinary standards is at the root of a vital and productive research environment. Institutions should strive to attain a research enterprise that emphasizes and rewards excellence in science, quality rather than quantity, openness rather than secrecy, and collegial obligations rather than opportunistic behavior in appointments, promotion, tenure, and other career decisions. The challenge is thus to aid faculty in establishing effective systems of values and social controls, to provide individuals with opportunities and incentives to develop and implement these systems, and to safeguard the traditions that foster scientific creativity.