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Institute of Medicine Research Integrity Report Analysis

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Integrity in Scientific Research *Creating an Environment that Promotes Responsible Conduct*

A Report of the Committee on Assessing Integrity in Research Environments

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THE STUDY

In response to a request from the Department of Health and Human Services' Office of Research Integrity (ORI), a special committee of the Institute of Medicine and National Research Council produced a report that focuses on institution's responsibilities to educate its members and create an environment that ensures integrity in research. As requested by ORI, the Committee attempts to define the concepts and identify the elements that promote integrity in research.

The goals of the Committee were to define desired outcomes and to set forth initiatives that would enhance research integrity in the research environment. Apart from the recommendations for future actions made by the Committee, the report makes several cogent observations that will have significant implications for the research community and will be critical in research institutions' implementation of the principles espoused in the report:

The overarching conclusion of the Committee, based on interviews, reports, presentations and review of relevant literature is that there are no rote solutions for the successful promotion of integrity in research.

Importantly, the Committee also observes that "...*The provision of instruction in the responsible conduct of research need not be driven by federal mandate*". The need for instruction should be derived from a fundamental premise of science: "...*that the responsible conduct of research is not distinct from research.*" Moreover, while federal mandates should set a floor of expectations for behavior, for educational programs and for institutional promotion of research integrity, it is up to the research institutions to develop an appropriate ethos for research and scholarly activity.

"Research integrity should be developed within the context of... an overall research education program." Based on this observation, the committee encourages a broad based approach to education in the responsible conduct of research, involving all levels of the institution. In that regard the committee urges that "...*Instruction in the responsible conduct of research is best done by faculty actively engaged in research related to that of the trainees.*"

The Committee makes it clear that it believes federal regulations or policies alone will not serve to promote integrity in the research environment. Regulations that set standards in specific areas of research activities – e.g., human research participant protections, animal welfare regulations, bio-safety standards – provide a useful framework but a mere regulatory approach to research integrity has "important limitations." Beyond increasing the administrative and scientific cost without a commensurate benefit, the Committee believes that regulations would fail to "*foster a*

deep understanding of the ethical issues involved and variety of sophisticated approaches available to address those issues.”

The Committee’s report presents recommendations that encourage research institutions to create programs that build an ethical climate and culture – an environment that promotes integrity – and to conduct rigorous, continuous assessment of the programs’ effectiveness. The federal government is only one of a number of external environments or factors that have an impact on the conduct of research and, ultimately, the integrity of that work. Other factors include the competitive funding for scientific work, the competitive nature of job and training opportunities, and journal and scientific policies and practices. All of these factors have either a direct or indirect impact on the institutions and their ability to create an environment that fosters integrity in research.

The Report contains six general recommendations. They fall short of ORI’s request for a more detailed outline of the elements that contribute to integrity, the types of data that can be drawn to measure these elements, the methodology that can be used for assessing the data, and appropriate measures or benchmarks to be used to determine a measure of success. In the absence of studies focused specifically on research integrity, the Committee draws on a broad range of complimentary theoretical works in preparing its recommendations. It points to research in areas like organizational behavior and ethical decision-making that offer a general framework to identify elements and approaches that create effective learning environments.

Recommendation 1:

Observing the scant empirical data and established measures available to “definitively support any one way to approach the problem of promoting and evaluating research integrity,” the Committee’s first Recommendation urges ORI and other funding agencies to establish grant programs “to identify, measure, and assess those factors that influence integrity in research.” As the Committee notes, ORI has begun to fund these types of studies and encourages expansion of these efforts by other agencies as well.

Recommendation 2:

In its second Recommendation, the Committee places the responsibility for ensuring the integrity of the research environment squarely on the research institution. It calls for universities and other research institutions to create a “comprehensive program to promote integrity in research, using multiple approaches adapted to the specific environments within each institution.” Outlining steps similar to those used by many universities to achieve the institution’s core missions and promote similar climate and learning goals, the Committee identifies some key elements of a institutional program for developing and maintaining an ethical culture and climate: supportive leadership; appropriate policies and procedures; effective educational programs; and thorough and continuous evaluation and assessment.

Recommendation 3:

Defining education as the key component of a program to promote integrity, the Committee's third Recommendation charges institutions to implement effective educational programs "built around the development of abilities that give rise to the responsible conduct of research." The Committee believes that this training should be provided by faculty actively engaged in research.

Recommendation 4 and 5:

Recommendations 4 and 5 focus on institutional self-assessment and external peer review. The Committee calls for a robust system of self-assessment ultimately linked to evaluation criteria in the higher education accreditation processes. But the Committee goes beyond an institutional-level program assessment calling for the integration of the goals of promoting integrity into all aspects of evaluation conducted on campuses – evaluations of deans, departments and individual faculty members. To ensure the credibility of the process, both internally and externally, the Committee emphasizes the need for external peer review. The Committee looks to the accreditation process as an opportunity to systematically conduct assessments and external reviews.

Recommendation 6:

The final Recommendation urges ORI to create an informational database of activities to build a resource for universities building their own programs and a demonstration for the public that universities are working to ensure research integrity.

LIMITATIONS OF THE STUDY:

The study directly addresses education of graduate students and postdoctoral fellows in the responsible conduct of research. It does this not because there is a sense that problems of research integrity lie in these populations but rather that educating future scientists and researchers will have the greatest long term benefit for the academic enterprise.

The draft November 2000 *PHS Policy on Instruction in the Responsible Conduct of Research* suggests that faculty and staff who play key roles in proposing, performing, reporting or reviewing research, or who receive research training should complete a program of training in the responsible conduct of research. The Committee's report does not provide education recommendations for faculty or staff but rather leaves the target audience for training to the institution.

The role of professional and scholarly societies is acknowledged but is not developed fully in the Committee's discussion. Professional societies have an important role in guiding members at all stages in their careers on communal norms. Professional societies, through their education programs and publications also provide key tools for establishing discipline-specific standards of behavior. Scientific and professional journals likewise provide standards and benchmarks of professional behavioral expectations that can be more real and immediate than education programs. As journals and societies further evolve their expectations there will be a real world assessment and known consequences of irresponsible behavior.

IMPLICATIONS FOR INSTITUTIONS:

As institutions and their faculty consider the IOM report, several suggestions for future action come easily to mind.

First among these is, involve faculty from all scholarly and scientific disciplines in establishing institutional program and policies for instruction in the responsible conduct of research. These groups should seriously consider the breadth of the target audiences. The faculty should serve as role models in the responsible conduct of research. Education in research integrity will become most effective when taught values are seen as being operative within the institution's research and scholarly programs.

Second, institutions should take care to tailor instructional programs to address discipline specific cultural norms. For example, authorship practices differ widely even among science disciplines, let alone across the humanities and the sciences.

Third, design flexible instructional activities based on principles of providing "students" with the "tools" to make ethical decisions in new situations based on prior experience and employ adult learning techniques that facilitate engagement of learners in the educational experience.

Fourth, use faculty as "instructors" and integrate the training/learning in ethical decision-making into the core research education curriculum. Training the faculty will be critical to the program's success if the training in ethical decision-making is to move beyond a seminar or sequence of seminars for students. Having engaged faculty will amplify the opportunities for more informal learning, e.g., in labs, "practicums", colloquia, etc. (implementing the "spaced review and practice" approach).

Fifth, assess individual faculty on integrity issues. The criteria used by individual departments in the annually or promotion assessments of their colleagues brings into sharp focus how the standards used by the university (e.g., dean) and the department in determining continuing employment are set. The development of criteria and, perhaps more importantly, measures to be used to assess those criteria will require careful and thoughtful collaboration between the faculty and academic leadership. Given the reported ambivalence of some faculty to receiving orientation in the responsible conduct of research this may prove to be a difficult challenge and will require a fair amount of discussion among faculty to achieve a consensus view. Some campuses with faculties represented by unions will need to build these issues into negotiations.

Ultimately, all of these activities including re-thinking the core research education curriculum will take a focused and extended period of time – time that some faculty will be unable or unwilling to commit. If the stakes are high enough – the incentives significant enough – to bring the faculty to the table, the institution must be prepared to provide sufficient support services and resources to assist the faculty.