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Ethics and Science: A 0.1% Solution

Science has an ethics problem. In South Korea, Woo Suk Hwang committed what is arguably the most publicized case of research misconduct in the history of science. The range of Hwang's misconduct was unusual but not extraordinary. He misjudged the ethical challenges presented by a newly developing field of research, he paid insufficient attention to accepted standards of responsible conduct, and he had a role in the fabrication of many key research findings. What made this case extraordinary was that it involved human embryonic stem cell research, a field of inquiry that is being watched more closely by the global public than perhaps any before it. The impact of this scandal is profound for Hwang, for his country, for all of science, and for stem cell research in particular.

The United States is not immune to cases of research misconduct. In one of several examples in 2005, Paul Kornak, a researcher with the Veterans Administration in Albany, New York, admitted that he had forged medical records. The forgeries made it possible for individuals to enter drug trials for which they were not qualified, and one of those individuals subsequently died, apparently as a result of his participation. Although cases such as this receive limited media attention, they deserve our attention as much as the case of Hwang. The problem we face is not just how to minimize the occurrence of such cases, nor is it just about the biomedical sciences and human health. The more fundamental problem is the need to define more clearly what constitutes responsible conduct in all areas of academic inquiry.

Standards of conduct should include much more than just avoiding behavior that is clearly illegal. During the past 15 years, numerous studies have provided evidence that on the order of one-third of scientists struggle with recognizing and adhering to accepted standards of conduct. This does not mean that large numbers of scientists are knowingly engaging in research misconduct, but it is reasonable to conclude that many lack the tools, resources, and awareness of standards that would serve to sustain the highest integrity of research. The pursuit of knowledge is a noble end, but we scientists owe more to the public and to ourselves than to ignore the ethical foundations of what we do. If we expect our colleagues to act responsibly, then we must provide them with the knowledge and support they need.

In academia, we recognize that the remedy for gaps in knowledge and skills is education and training. Because the purpose of science is to have an impact on the human condition, the conduct of science is defined by ethical questions. What should be studied, what are the accepted standards for the conduct of research, and what can be done to promote the truthful and accurate reporting of research? The answers to these questions are not normally found in a K-12 education or in college. Based on surveys of researchers, these questions are only rarely being answered through research training. Something more is required. Institutions of higher education are the logical places to fill this gap.

In the area of research ethics, scientists have obligations to the public that grants them the privilege to conduct research, to private and public funders who expect that research will be conducted with integrity, to the scientific record, and to the young people they train. These are not mere regulatory obligations; they are also the right thing to do. That said, these obligations are addressed in part by a National Institutes of Health (NIH) requirement, now in place for 15 years, that those supported by NIH training grants should receive training in the responsible conduct of research

(RCR). The domain of RCR training includes not only the ethical dimensions of research with human subjects, but every dimension of responsible conduct in the planning, performance, analysis, and reporting of research. This RCR requirement stimulated the creation of educational materials and resources and encouraged the participation of research faculty in the teaching of RCR courses.

Such a requirement is appropriate and important, but limiting the required training to the select few that receive NIH funding unintentionally sends the wrong message. Under these circumstances, it is not unexpected for faculty and trainees to assume that RCR training is just one more bureaucratic hurdle rather than something that has real value. The way to remedy this perception is to implement training programs that engage all researchers.

Expanding RCR training to all will not be easy. In December 2000, the Office of Research Integrity (ORI) and the Public Health Service (PHS) announced that all researchers supported by PHS grants would be required to receive RCR training. Many in the academic community were justifiably unhappy that the policy was a highly prescriptive and unfunded "one size fits all" mandate. The requirement was suspended in February of 2001, just two months after its announcement. The ORI's decision to suspend the requirement was precipitated by concerns that it had not been developed through appropriate rulemaking procedures. Whatever the shortcomings of that effort, the need for RCR training for all researchers still exists.

Before the requirement was suspended, an RCR education summit was convened by multiple federal agencies. The goal of the summit was to address the roles of the federal government and federally funded research institutions in meeting a common interest in effective RCR education for all scientists. In that meeting, Jeffrey Cohen, who was then director for education at the Office for Human Research Protections, clearly articulated the apparent dilemma. On the one hand, a federal requirement for RCR education could readily result in a prescriptive and inflexible program that would not be effective. On the other hand, in the absence of a federal mandate, research institutions had only rarely created programs to promote RCR.

The good news is that the initial announcement of a requirement stimulated many institutions to begin developing programs for RCR training. Unfortunately, once the requirement was suspended, efforts to enhance RCR education slipped down the list of priorities. The U.S. experience appears to be that although research institutions talk about the importance of ethics, most are funding little more than what is required for compliance. Today, the challenge for the research community is to promote RCR education in the absence of a regulatory mandate.

Continuing with the status quo is not good enough. Or more precisely, funding only the minimum required to comply with external regulations is inadequate. However, although an increased focus on ethics is an admirable goal, resources are scarce. If we hope to do more to promote ethics, then the inevitable question is what will it cost? We could begin by a prescriptive listing of what must be done and then ask how much those programs would cost. However, general implementation of this approach is impractical if only because circumstances in each institution vary so greatly.

A better formula would be to make ethics support commensurate with the size of the research program. A similar approach was carried out with the allocation of 3% of the Human Genome Project research budget to study its ethical, legal, and social implications. Given the necessary resources, each institution could then implement the kinds of programs most appropriate to its culture and needs. Unfortunately, it is unlikely that today's research institutions can realistically consider a 3% allocation in the face of declining research budgets. So if not 3%, how much?

In health care policy, a "decent minimum" is often discussed as a standard for judging what should be in place for everyone. Given the need for an increased focus on the ethical dimensions of research, it is reasonable to ask what would be a decent minimum above what is currently allocated for compliance. Using the principles that funding should be proportional to the research budget and that formal programs are critical for addressing the ethical dimensions of research, I propose that we begin with a requirement of spending just 0.1% of an institution's direct research funding for RCR education.

What could be done with such a modest allocation for research ethics? Intermediate and large research institutions would have dedicated resources to create and carry out a variety of programs to train researchers, to raise awareness of ethical issues and resources, and to engage the public in a shared examination of the ethical and scientific foundations for ongoing and proposed research. Smaller institutions could use their more limited resources to develop partnerships with other institutions and to attend train-the-trainer programs rather than develop programs de novo. In addition, smaller institutions could obtain help with program creation through organizations such as the Association for Practical and Professional Ethics (http://www.indiana.edu/~appe), the Collaborative IRB Training Initiative (https://www.citiprogram.org), the Responsible Conduct of Research Education Consortium

(http://rcrec.org), and the Society of Research Administrators International (http://www.srainternational.org).

This year marks the fifth anniversary of the suspension of the PHS requirement for RCR training for the researchers it funds. Rather than continuing to wait for federal action, the research community should take the high ground and exhibit the necessary leadership to ensure that ethics is an integral part of science. The cost of 0.1% is low, and the potential for gain is high. Experience will determine whether the amount is adequate, but it should be possible to win wide agreement that it is a good starting point for a decent minimum.

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