EDITORIAL

Some Thoughts on the Ethics of Research and Publication

In recent years, discussions of the ethical issues associated with the conduct of research and the publication of scientific papers have moved from the hallways of academia to the floor of the U.S. Congress, the General Assembly of the United Nations, and the front pages of newspapers around the world.

At one time, individual scientists were guided primarily by their own consciences and moral frameworks in considering the ethical issues related to their research. Publication was similarly casual, and often consisted of reporting experimental findings in talks at one’s own institution and circulating manuscripts to colleagues elsewhere. “Peer review” occurred after publication, and focused on the discussion, replication and extension of published findings, rather than on the pre-review of proposed projects and the critiquing of scientific manuscripts being evaluated for possible publication in scholarly journals. Those days are gone.

Today, the institutions where research is performed and the governmental agencies, charitable organizations, and commercial entities that sponsor research are under increasing pressure to ensure that the research performed under their auspices proceeds with appropriate regard for the many ethical considerations encountered during the planning and performance of the research and during the dissemination of the research findings. Moreover, scholarly journals are being called upon to ensure that the papers they publish have been prepared with appropriate consideration for the ethical issues involved in publication and to ensure that the research reported in these papers has been performed ethically and with appropriate regard for the welfare of any human subjects or animals involved in the research. In response to this, the new issue of the “Uniform Requirements for Manuscripts Submitted for Biomedical Publication”, to be published by the International Committee of Medical Journal Editors early this year, will include an enhanced section on the ethics of publication (see http://www.icjme.org/).

New and ever more stringent regulations, policies and guidelines are being issued concerning the pre-review of potential research projects and the oversight of research. In the U.S., Congress, the U.S. Public Health Service, and the Food and Drug Administration have been among the organizations implementing new directives related to the oversight of research using human subjects. These go far beyond the ethical principles outlined in the original Nuremberg code and the Belmont Report. They include detailed prescriptions for procedures that must be followed to ensure, and to document the assurance of, the protection of the health, welfare and privacy of human subjects. Concerns about privacy and about the potential stigmatization of individuals or groups of people have recently brought many studies with human tissues and cells and many epidemiological studies under the umbrella of the regulations governing human subjects research and have added new dimensions to the ethical review of such studies.

Research using animals likewise has been scrutinized increasingly by national agencies (in the U.S., including the Public Health Service Office of Laboratory Animal Welfare, the Food and Drug Administration and the Department of Agriculture) and is increasingly regulated by national, state and local laws and by rules and policies imposed by research institutions, funding agencies, and accreditation agencies. These require pre-review and monitoring of experiments using animals, not only to ensure that the use of animals in the experiments is ethically justified, but also to ensure that the experimental protocols are sound, that the researchers have appropriate skills, knowledge and access to veterinary expertise, and that the handling, husbandry and housing of the animals are suitable and appropriate.

Formal mechanisms for identifying and dealing with scientific misconduct and fraud have been developed and implemented at local and national levels. At present, problems related to real, potential and apparent conflicts of interest in research, medicine, teaching and publication are under considerable discussion in many venues and countries around the world. Expectations for disclosure and procedures for management of potential conflicts of interest are evolving rapidly and continually. Different regulatory agencies have proposed different (and often conflicting) standards and policies.

The conflicting, confusing and continually changing policies and regulations related to the ethics and oversight of research are a source of concern and frustration for many researchers. However, we must be sensitive to the realities that have lead to the current situation. The evolving discussion, regulation and oversight of the ethics of research did not occur in a vacuum. Instead it has been fueled by specific instances of questionable practices and frankly unethical behaviors and by the tragic and avoidable deaths of healthy volunteers participating in research protocols. These have been widely reported both in scholarly journals and in the popular press. We cannot ignore these situations. We cannot pretend that they do not exist. We cannot even assume that they could never extend to studies in the radiation sciences. Indeed, thoughtful evaluations performed by a panel that included members of our own research community have provided evidence to the contrary (1).

Moreover, we live in a time when the media and the public are gravely concerned about the potential problems, dangers and