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Research Ethics Consultation at the National Institute of Environmental Health Sciences

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In their target article “Strangers at the Benchside: Research Ethics Consultation,” Mildred Cho et al (2008) provide a useful overview of different approaches to research ethics consultation, the Stanford model of consultation, and some of the problems and concerns related to consultation. In this response, I will describe research ethics consultation at the National Institute of Environmental Health Sciences (NIEHS) and discuss some of the related to my work as a research ethics consultant.

The NIEHS is a branch of the National Institutes of Health (NIH) located in Research Triangle Park, NC. Research funded by the NIEHS ranges from basic biomedical research to clinical research and epidemiologic studies. The NIEHS has an extramural program, which funds research conducted by investigators from a variety of disciplines conducted at universities and college campuses, and an intramural program, which supports research conducted by investigators who are employees of the NIEHS. The intramural program supports over 600 researchers organized into five categories: environmental biology, environmental disease and medicine, clinical research, environmental toxicology, and the National Toxicology Program (NTP). The NTP, which is supported by the NIEHS, the National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention (NIOSH/CDC), and the National Center for Toxicological Research of the Food and Drug Administration (NCTR/FDA), is administered by the Director of the NIEHS.

The NIEHS hired its first bioethicist, Richard Sharp, in 1997, to help researchers think about the social and ethical issues raised by the Environmental Genome Project. Dr. Sharp soon began to perform a variety of bioethics-related duties for the NIEHS. He served on the institutional review board (IRB) and conducted bioethics pre-review of human subjects protocols submitted to the IRB, conducted the annual required training sessions in responsible conduct of research (RCR), organized bioethics seminars and conferences, directed the Program in Environmental Health Policy and Ethics, an internship program for students who were interested in pursuing careers in health policy and bioethics, consulted with researchers on ethics issues, and conducted bioethics research.

When Dr. Sharp left the NIEHS to take a position at the Baylor College of Medicine in 2002, the Scientific Director of the NIEHS realized that it would be useful to continue to have a bioethicist on-site, since the NIEHS does not have easy access to bioethicists who work at the NIH's main campus in Bethesda, MD. In 2004, the NIEHS hired David Resnik (me) to replace Richard Sharp. Since coming to the NIEHS, I have performed most of the functions performed by Dr. Sharp. Additionally, I was named Vice-Chair of the IRB in 2006, and I have worked with the IRB Chair, Marian Johnson-Thompson, and IRB Administrator, Jane Lambert, on human research ethics and compliance issues. I have also served on several committees, including the trans-NIH Bioethics Committee, the NIH Committee on Scientific Conduct and Ethics, and the NIEHS Research Ethics Committee.

One of my primary responsibilities at NIEHS is to consult with investigators, trainees, and staff on ethical issues in research. I publicize my consultation services during the annual training sessions in RCR and during bioethics seminars at the NIEHS. Researchers can contact me by phone or email, and there is a bioethics link on the intramural research web-page listed under “scientific resources” (<http://inside-www.niehs.nih.gov/junction/science.htm>). I offer confidential consultation with some limitations (discussed below). Requests for consultation have come from principal investigators, staff scientists, post-doctoral fellows, contractors, laboratory directors, and administrators. I have consulted with researchers on human research ethics issues, such as risks and benefits, informed consent, confidentiality, vulnerable subjects, payments to subjects, and biobanking; and RCR issues, such as authorship, mentoring, laboratory relationships, data management, conflicts of interest, intellectual property, publication, and research misconduct.

I have conducted an average of 36 consultations per year, consisting of about two-thirds human research ethics issues and one-third RCR issues. The consultations have taken place in my office, in conference rooms, by phone, or through email. Most of the consultations occur informally, when researchers contact me about an issue or problem. Some of the consultations occur in a more formal way, when researchers submit human subjects protocols to the IRB. The NIEHS requires that all human subjects protocols undergo scientific review and bioethics review prior to IRB review. I offer researchers information and advice but do not make decisions for them or tell what they must do. However, in cases involving potential violations of NIH policies, I have strongly recommended that researchers avoid violating those policies.

Cho et al (2008) discuss the different models of research ethics consultation, ranging from the single expert to the consultation team. Both forms of consultation occur at the NIEHS. For many of the human research ethics consultations, more than one person may be involved, such as the IRB Chair, the IRB administrator and another IRB member or two, and me. RCR consultations usually conform to the single expert model. In a typical consultation, someone will contact me by email or phone and we will set up a time to meet in my office. I am usually available on short notice. Cho et al (2008) address the issue of whether a single person would have sufficient background in science and the humanities to serve as a single expert consultant. I have a strong humanities background, with an MA and PhD in philosophy, and JD in law. Though I do not have a science degree, I have studied biomedical science in college and graduate school, and I have continued to learn more about biomedicine and biotechnology during my career. I consider my science background sufficient to understand the scientific context of the ethical, social, and legal issues that are presented to me.

The bioethics consultation I perform at the NIEHS can help researchers in several ways. First, sometimes the issue the researchers want help with is not really a bioethics issue at all but is another type of issue, such as a government ethics issue. The NIH has a variety of government ethics rules pertaining to such issues as outside activities, ownership of stock, gifts, conflicts of interest, and so on. When researchers come to me with these issues, I refer them to the appropriate person in the NIEHS or NIH for help.

Second, sometimes there are specific NIH policies or guidelines, or federal regulations that bear on the issues being discussed. For example, when I am asked to help researchers deal with authorship issues, I usually inform them about the NIH's policy on authorship and I help them interpret it. The NIH (2007) has recently revised its *Guidelines for the Conduct of Research*. The guidelines include not only policies on authorship, but also policies on publication, mentoring, data management, research misconduct, human subjects research, animal research, conflicts of interest, collaboration, and peer review. If a researcher has a question about a study involving human subjects, I usually can refer to specific NIH policies or federal regulations

pertaining to human subjects research. The NIH's Office of Human Subjects Research (OHSR) has a variety of policies, guidelines, and resources pertaining to research with human subjects.

Third, when there are no policies, guidelines, or regulations that apply to the situation being discussed, or these have limited applicability, I can help researchers think about the ethical issues at a more fundamental level. In this role, I seldom refer to ethical theories, but I have often mention ethical principles, such as respect for persons, beneficence, justice/fairness, honesty, confidentiality, and social responsibility. I try to help researchers think about the options available to them, the information they may need to help them make a decision, and the reasons for choosing one option over another.

Fourth, sometimes I help researchers by serving as a sounding board or sympathetic ear. Researchers want not only information about policies, guidelines and ethical considerations, but they also want some additional discussion, clarification, or understanding. On more than a few occasions researchers have thanked me for listening to their problems or giving them some assurance. Sometimes researchers are dealing with issues or problems that result from organizational factors over which they have very little control, such as the role of the technician in a laboratory or attitudes toward women or minority groups, which can lead to feelings of frustrations or despair. In some situations, I have suggested that researchers take some positive steps to deal with or try to change the circumstances that have led to their ethical difficulty, and I have recommended that they get additional help from someone else in the NIH, such as the Scientific Director of the NIEHS or the NIH Ombudsman's Office.

I sometimes encounter ethical dilemmas relating to my role as a bioethicist. Cho et al (2008) allude to one of the problems I have faced a few times. As mentioned earlier, I offer confidential consultation. I believe that confidentiality is very important so that researchers can talk freely, without any fear of consequences or repercussions. But this promise of confidential consultation may conflict with my ethical or legal obligations to report suspected violations of NIH policies, federal regulations, or other legal or ethical rules. If someone describes a situation that appears to be a case of data fabrication, I would need to decide whether to report this incident to the appropriate person in the NIH, and violate confidentiality, or ignore the information and abdicate my responsibility to help the NIEHS comply with relevant policies and regulations. The way I usually get around this dilemma is to tell people up front that I can only promise confidentiality within limits, since I am obligated to report legal or ethical violations that I learn about during consultation. I inform researchers that if they are concerned about informing me about legal or ethical violations, they can discuss their situation in the abstract (without mentioning specific names) or they can talk about it as a hypothetical scenario. This will allow me to help them think about their situation without giving me enough information to trigger my obligation to report suspected ethical or legal violations.

Some of the other dilemmas result from the conflicts of interest that I have as an ethics consultant working for an organization. Cho et al (2008) also mention these dilemmas. One question I sometimes face is whether to take any action to address organizational factors that have played a role in creating ethical problems or issues for NIEHS researchers. Should I take steps to push for change or should I remain neutral? If I push for change, I may alienate leaders of the NIEHS and others who support the bioethics program, but if I remain neutral I would be ignoring my ethical obligations to improve the ethical culture of the organization and prevent ethical problems. So far, I have chosen to remain neutral in most cases, but I have encouraged those who have sought my advice to consider taking some steps to change the organizational factors that contributed to their problems.

Another dilemma I sometimes encounter is how to handle a situation in which I am asked to participate in a consultation involving someone at the institute who has some authority over

me. This situation has occurred in the IRB's review of human research protocols. The NIH has decided to handle this problem by having another NIH IRB review research protocols that are submitted by the NIEHS Director or Scientific Director, thus relieving IRB members of a conflict of interest that could impair their ability to fair and unbiased decisions.

In closing, I would like to observe that Cho et al's (2008) title phrase "Strangers at the Benchside" does not describe research ethics consultation at the NIEHS. Since I am responsible for conducting annual RCR training sessions at the NIEHS, I am no stranger to most of the people who seek my assistance. I have gotten to know many NIEHS researchers quite well, through research collaborations, service on committees, and participation in the intellectual life of the institute. During my first year at the NIEHS I felt a little out of place, but after nearly four years here I feel that I have become integrated into organization, and that researchers respect and value my advice.

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