April 22, 2011

Public Commentary
The Presidential Commission for the Study of Bioethical Issues
1425 New York Ave., NW
Suite C-100
Washington, DC 20005
Info@bioethics.gov


Dear Members of the Presidential Commission:

Public Responsibility in Medicine and Research (PRIM&R) appreciates the opportunity to submit comments to the Presidential Commission regarding Human Subjects Protections in Scientific Studies, per the March 2, 2011 Federal Register Notice.

PRIM&R is a non-profit organization dedicated to advancing the highest ethical standards in the conduct of research. Since 1974, PRIM&R has served the full array of individuals and organizations involved in biomedical, social science, behavioral, and educational research. PRIM&R’s membership community includes professionals representing human subjects protection, animal care and use, and institutional biosafety programs, as well as researchers, institutional officials, government personnel, subject advocates, ethicists, policy makers, pharmaceutical and biotechnology leaders, and attorneys. Via a wide variety of conferences and other educational activities, PRIM&R provides balanced, thorough, and accurate information on a range of ethical and regulatory issues affecting research, while also offering access to certification, networking, and professional development resources.

The Commissions’ request for “advice and comments” on the entire spectrum of human subjects’ protections issues casts a very broad net. We have therefore chosen to focus on what we consider to be one of the key issues, i.e., the implementation of the current regulatory requirements for obtaining and documenting informed consent. PRIM&R believes strongly in the primacy of subject autonomy as a core value, and further believes that it is absolutely essential for research subjects to be informed about the purpose, risks, benefits, and alternatives to participating in a proposed research study. However, based on comments made by innumerable presenters and attendees at our conferences, it is PRIM&R’s
view that the processes of informed consent and its documentation are seriously broken. PRIM&R has three specific areas of concern.

First, it has become increasingly apparent that the consent process is not being primarily used to inform potential subjects but rather to protect the institutions that are required to abide by the current policies to avoid regulatory or other legal sanctions. Protecting institutions was not the original goal of the informed consent process—the goal was the protection of prospective subjects; but this goal has been subverted.

Second, as a result of this increasingly legalistic and compliance-driven approach, we have seen a trend toward producing longer and increasingly complex consent forms, with decreasing attention being paid to truly informing potential subjects about the proposed research and gauging their understanding. A growing consensus in the human research protections field is that there is too much emphasis on full disclosure for disclosure’s sake. The consent forms that result from this misplaced emphasis have become a barrier, rather than an aid, to a prospective subject’s understanding. It is not uncommon, particularly in complex clinical trials, to see 15-, 20-, or 25-page consent documents filled with highly technical, difficult to understand, and at times repetitive language. Such documents often confuse rather than “inform” potential research subjects about what they are being asked to do.

Third, despite some flexibility in the regulatory language, the prevailing interpretation of the regulations seems to be that they require the process of informed consent to take one particular approach. But it is misguided to think that one model of consent fits all research: different types of research—for instance, genomewide association studies, research on stored tissue samples, survey research in social science—warrant different approaches to the consent process and its documentation. This problem is often exacerbated in international settings where, for instance, local cultural norms may not recognize writing one’s name on a piece of paper as having meaning, let alone as a sign of having agreed to take on the burdens of being a research subject. In areas where illiteracy is the norm, attempting to communicate in writing is an altogether useless exercise. While the regulations themselves seem to have some flexibility built into them with respect to how consent is obtained and documented, institutions are very wary of implementing that flexibility. PRIM&R suggests several reasons for this. First, guidance and compliance letters from federal agencies such as the Office of Human Research Protections (OHRP) and the FDA can shape the interpretation or implementation of the regulations in unnecessarily narrow ways. Second, this can be the end result of a “culture of a compliance”-driven approach, in which the goal is to protect the institution, in contrast to an ethics-driven approach, in which the goal is to protect subject autonomy.

Given our strong belief that paper forms are increasingly counterproductive and burdensome, PRIM&R urges the Commission to explore alternative models to obtain and document informed consent. Since the relevant regulations were first adopted 40 years ago, inexpensive technologies have become readily available, including digital audio- and video-recording technologies which provide simpler and more effective means of documenting the actual consent interaction that takes place between the investigator and the potential subject.
Another trend that could be effectively utilized in the service of better informing prospective subjects is the use of technology for education. Written manuals are increasingly being replaced by technologies that provide more understandable information in a more user-friendly manner than lengthy written documents. When technology is combined with knowledgeable, accessible, and ethically anchored researchers and research staff, it is possible to foster genuine understanding and obtain meaningful consent without using a form at all. Indeed, a new approach may lead to a new mindset in which we move from “informed consent” to “educated consent,” which is the true underpinning for the protection of autonomy.

Thank you again for the opportunity to respond to the recent Federal Register Notice. We would be happy to expand further upon our comments if that would be helpful, and would also be happy to work with the Commission in any way that would be useful as it undertakes its important work.

Respectfully submitted,

Joan Rachlin, JD, MPH
Executive Director
Public Responsibility in Medicine and Research (PRIM&R)

Cc: Board of Directors, Public Policy Committee