July 20, 2015

Amy Gutmann, PhD
Presidential Commission for the Study of Bioethical Issues
1425 New York Avenue NW, Suite C-100
Washington, DC 20005

RE: Document 2015-09172, Request for Comments on Deliberation and Bioethics Education (80 FR 22209)

Dear Professor Gutmann:

As Executive Director of Public Responsibility in Medicine and Research (PRIM&R), a nonprofit educational and professional development organization dedicated to advancing the highest ethical standards in the conduct of research, I appreciate the opportunity to submit comments on the topic of bioethics education, as requested in the Federal Register on April 21, 2015. Specifically, the comments below speak to the importance of research ethics education in the context of continuing professional education, and the role of professional certification programs.

PRIM&R is the professional home to more than 4,000 people worldwide who are charged with the protection of human subjects in research and the care and use of research animals. We serve the full array of individuals and organizations involved in biomedical, behavioral, and social science research, particularly the members and staff of human research protection programs (HRPPs)/institutional review boards (IRBs) and institutional animal care and use committees (IACUCs). Since our founding in 1974, we have pursued two core goals: (1) creating a strong and vibrant community of ethics-minded research administration and oversight personnel, and (2) providing educational and professional development opportunities that offer this community the ongoing knowledge, support, and interaction it needs to raise the bar of research administration and oversight above regulatory compliance.

PRIM&R strongly believes that continuing professional education is essential for cultivating a climate that supports the ethical conduct of research. To that end, PRIM&R has, for more than 40 years, executed conferences and other educational activities, including online educational programs, webinars, and one-day short courses, designed to provide balanced, thorough, and accurate information on the range of ethical and regulatory issues affecting research. PRIM&R has also played a pivotal role in formalizing professional standards that codify the expertise necessary for the promotion of ethical research and effective and appropriate research administration and oversight.

In the late 1990s, as the research landscape in the United States expanded and concerns about noncompliance came to the fore, the need to strengthen the quality and consistency of research oversight became clear. To meet that need, in 1999, PRIM&R developed the Certified IRB Professional (CIP®) credential, which established an accepted body of knowledge and national standards of practice for individuals responsible for administering,
performing, or overseeing the daily activities of an HRPP/IRB. In 2006, PRIM&R expanded this effort with the creation of the Certified Professional IACUC Administrator (CPIA®) credential, which established, in turn, an accepted body of knowledge and national standards of practice for IACUC administration. Today, nearly 500 individuals have earned the CPIA credential, while more than 2,600 have earned the CIP credential.

Over the past 16 years of administering credentialing programs, PRIM&R has seen firsthand how professional certifications for individuals involved with the administration of research protection programs help increase adherence to regulatory requirements, foster the development and implementation of best practices, and promote the application of ethical principles, all serving to strengthen not just research oversight, but the research programs of the institutions that employ credential holders.

For example, credential holders report that by becoming certified, they have grown more confident in their decision-making and self-assured in the workplace, attributes that leave them better equipped to foster an institutional climate that supports the ethical conduct of research. Relatedly, individuals have reported that by becoming certified they are able to garner greater respect from their peers, including researchers and study personnel, because they are able to demonstrate that they possess a specialized knowledge base about research ethics and oversight. Mutual respect, in turn, helps to foster teamwork, collaboration, and, ultimately, a climate that supports the ethical conduct of research. The institutions that employ credential holders further benefit from having a professionally managed HRPP/IRB or IACUC, which strengthens the operations of their research protections programs, resulting in greater consistency, efficiency and, most importantly, enhanced subject protections. Finally, individuals who successfully earn and maintain the CIP and CPIA credentials are able to signal to research institutions, the public, and members of the human subjects research and animal care and use professions that they are highly qualified to discharge their duties pursuant to United States rules and regulations, prevailing ethical codes, and administrative best practices, a fact that serves to enhance public trust in the research enterprise.

PRIM&R firmly believes that continuous professional education for those who are tasked with protecting human research subjects and overseeing the care and use of laboratory animals, especially in the form of professional credentialing programs, plays an integral part in advancing good, ethical research with humans and animals. We are proud of the role we have played in the development of initiatives that support that aim.

Thank you for the opportunity to comment on this topic. I hope that you and your colleagues have found my input on this matter useful. If you have questions or require further information, please feel free to contact me at (617) 423-4112, ext. 122, or ehurley@primr.org.

Respectfully Submitted,

Elisa A. Hurley, PhD
Executive Director

cc: Board of Directors