March 26, 2014

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

RE: Document 2014-02072, Request for Comments on the Ethical Considerations of Neuroscience Research and the Application of Neuroscience Research Findings (79 FR 5412)

Dear Dr. Gutmann:


For 40 years, PRIM&R has been dedicated to advancing the highest ethical standards in the conduct of research. We accomplish this goal by serving 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) and institutional review boards (IRBs). Through conferences and other educational activities, PRIM&R provides balanced, thorough, and accurate information on a range of ethical and regulatory issues affecting research.

While we understand that the Bioethics Commission is exploring ethical issues related both to neuroscience research and to the applications of neuroscience findings, our comments are limited to matters arising in research.

Within that context, PRIM&R strongly urges the commission to start by recognizing that the ethics of neuroscience research is not distinct from the ethics of research in other areas of biology and medicine. Correspondingly, we believe that it would be a mistake to think that neuroscience research requires a unique set of guiding ethical principles distinct from the principles of research ethics generally.

Recent federal initiatives have placed renewed emphasis on brain research, and much of that research uses innovative methods and targets novel brain systems. Nevertheless, we urge the Bioethics Commission to approach the promulgation of new ethical standards to guide those efforts critically and skeptically. There is no reason to think that the ethical principles applicable to biomedical research with human subjects generally—including, at least, respect for persons,
beneficence, and justice—will not adequately address issues posed by emerging neuroscience research. Repackaging ethical standards into specialized subcategories (such as “neuroethics”) is neither necessary nor likely to produce better review of the research or better understanding of the issues involved, and we caution the Bioethics Commission against proceeding in this manner.

To the extent that neuroscience research may involve individuals with impaired decision-making capacity, it will raise important ethical questions related to the special vulnerability—actual or potential—of such subjects. Again, this does not present new issues. Indeed, there is a robust body of scholarship and policy recommendations on these very issues to be found in the work of prior national commissions as well as the Secretary’s Advisory Committee on Human Research Protections. We encourage the Bioethics Commission to revisit the reports and recommendations prepared by those advisory bodies, as they speak to how to apply the existing ethical and regulatory framework to at least a subset of neuroscience research. We believe your commission could benefit not only from reviewing the substantive conclusions reached by predecessor bioethics bodies on this type of research, but from analyzing why their recommendations have not been more fully incorporated into existing regulations and guidelines on the ethics of research.

Your commission indicated its interest in receiving public comment on the “core ethical standards that guide neuroscience research, including consistency (or lack thereof) across disciplines, and potential tension among the guiding standards.” We suggest that the principles of research be consistent across all areas of biomedical investigation, as this is the best way to minimize tension amongst guiding standards and regulations.

PRIM&R is grateful for the opportunity to comment, and we hope that you and your colleagues will find our input on this matter to be useful as you continue your work examining the ethical considerations of neuroscience research. If you have any questions or require any further information, please feel free to contact me at (213) 740-2557 or our incoming Executive Director, Dr. Elisa Hurley, at (617) 423-4112 or ehurley@primr.org.

Respectfully Submitted,

Alexander M. Capron
Board Chair

cc: Board of Directors