

Bioethics commission plays early role in BRAIN Initiative

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Calling for the integration of ethics across the life of neuroscientific research endeavors, the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission) released volume one of its two-part response to President Obama's request related to the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative. The report, [*Gray Matters: Integrative Approaches for Neuroscience, Ethics, and Society*](#), includes four recommendations for institutions and individuals engaged in neuroscience research including government agencies and other funders.

"Neurological conditions—which include addiction, chronic pain, dementia, depression, epilepsy, multiple sclerosis, Parkinson's disease, schizophrenia, stroke, and traumatic brain injury, among other conditions—affect more than one billion people globally. Neuroscience has begun to make important breakthroughs, but given the complexity of the brain, we must better understand it in order to make desired progress," said Amy Gutmann, Ph.D., Bioethics Commission Chair. "But because research on our brains strikes at the very core of who we are, the ethical stakes of [neuroscience research](#) could not be higher. Ethicists and scientists should be together at the table in the earliest stages of research planning fostering a fluent two-way conversation. Too often in our nation's past, ethical lapses in research have had tragic consequences and derailed scientific progress."

President Obama asked the Bioethics Commission to play a critical role in ensuring that neuroscientific investigational methods and protocols are

consistent with sound ethical principles and practices. Specifically the President asked the Bioethics Commission to "identify proactively a set of core ethical standards – both to guide [neuroscience](#) research and to address some of the ethical dilemmas that may be raised by the application of neuroscience research findings."

"Our rapidly advancing knowledge of the nervous system – and ability to detect disease sometimes even before symptoms begin – has not yet led to much needed breakthroughs in treatment, repair, and prevention; the BRAIN initiative will hopefully accelerate the trajectory of discoveries against terrible neurologic maladies," Commission Member and neuroimmunologist Stephen Hauser, M.D., said.

In its report the Bioethics Commission noted that when facing the promise of neuroscience, we are compelled to consider carefully scientific advances that have the potential to alter our conception of the very private and autonomous nature of self. Our understanding of the mind, our private thoughts, and our volition necessitates careful reflection about the scientific, societal, and ethical aspects of neuroscience endeavors. Integrating [ethics](#) explicitly and systematically into the relatively new field of contemporary neuroscience allows us to incorporate ethical insights into the scientific process and to consider societal implications of neuroscience research from the start. Early ethics integration can prevent the need for corrective interventions resulting from ethical mishaps that erode public trust in science.

"In short, everyone benefits when the emphasis is on integration, not intervention," Gutmann said. "Ethics in science must not come to the fore for the first time after something has gone wrong. An essential step is to include expert ethicists in the BRAIN Initiative advisory and review bodies."

Recommendations

In its report the Bioethics Commission noted that although ethics is already integrated into science in various ways, more explicit and systematic integration serves to elucidate implicit ethical judgments and allows their merits to be assessed more thoughtfully. The Commission offered four recommendations.

1. Integrate ethics early and explicitly throughout research:
Institutions and individuals engaged in neuroscience research should integrate ethics across the life of a research endeavor, identifying the key ethical questions associated with their research and taking immediate steps to make explicit their systems for addressing those questions. Sufficient resources should be dedicated to support ethics integration. Approaches to ethics integration discussed by the Bioethics Commission include:
 - a. Implementing ethics education at all levels
 - b. Developing institutional infrastructure to facilitate integration
 - c. Researching the ethical, legal, and social implications of scientific research
 - d. Providing research ethics consultation services
 - e. Engaging with stakeholders
 - f. Including an ethics perspective on the research team
2. Evaluate existing and innovative approaches to ethics integration:

Government agencies and other research funders should initiate and support research that evaluates existing as well as innovative approaches to ethics integration. Institutions and individuals engaged in neuroscience research should take into account the best available evidence for what works when implementing, modifying, or improving systems for ethics integration.

3. Integrate ethics and science through education at all levels: Government agencies and other research funders should initiate and support research that develops innovative models and evaluates existing and new models for integrating ethics and science through education at all levels.
4. Explicitly include ethical perspectives on advisory and review bodies: BRAIN Initiative-related scientific advisory and funding review bodies should include substantive participation by persons with relevant expertise in the ethical and societal implications of the neuroscience research under consideration.

Next the Bioethics Commission will consider the ethical and societal implications of neuroscience research and its applications more broadly – ethical implications that a strongly integrated research and ethics infrastructure will be well equipped to address, and that myriad stakeholders, including scientists, ethicists, educators, public and private funders, advocacy organizations, and the public should be prepared to handle.

Gray Matters: Integrative Approaches for Neuroscience, Ethics, and Society is the Bioethics Commission's seventh report. The Commission seeks to identify and promote policies and practices that ensure that scientific research, health care delivery, and technological innovation are conducted by the United States in a socially and ethically responsible manner. The Commission is an independent, deliberative panel of thoughtful experts that advises the President and the Administration, and, in so doing, educates the nation on bioethical issues. To date the

Commission has:

- Advised the White House on the benefits and risks of synthetic biology;
- Completed an independent historical overview and ethical analysis of the U.S. Public Health Service STD experiments in Guatemala in the 1940s;
- Assessed the rules that currently protect human participants in research;
- Examined the pressing privacy concerns raised by the emergence and increasing use of whole genome sequencing;
- Conducted a thorough review of the ethical considerations of conducting clinical trials of medical countermeasures with children, including the ethical considerations involved in conducting a pre-and post-event study of anthrax vaccine adsorbed for post-exposure prophylaxis with children; and
- Offered ethical analysis and recommendations for clinicians, researchers, and direct-to-consumer testing companies on how to manage the increasingly common issue of incidental and secondary findings.

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