

Obama Administration Proposes Over \$300 Million in Funding for The BRAIN Initiative

"Last year, I launched the BRAIN Initiative to help unlock the mysteries of the brain, to improve our treatment of conditions like Alzheimer's and autism and to deepen our understanding of how we think, learn and remember. I'm pleased to announce new steps that my Administration is taking to support this critical research, and I'm heartened to see so many private, philanthropic, and academic institutions joining this effort."

 President Barack Obama Sept. 2014

Since its launch in April 2013, the President's BRAIN Initiative - Brain Research through Advancing Innovative Neurotechnologies – has grown to include investments from five federal agencies with the Intelligence Advanced Research Projects Activity (IARPA) joining the Defense Advanced Research Projects Agency (DARPA), the National Institutes of Health (NIH), the National Science Foundation (NSF), and the Food and Drug Administration (FDA).

There has been an enthusiastic response to the President's call for an "all hands on deck" effort. Major foundations and private research institutions, including the Howard Hughes Medical Institute, Allen Institute for Brain Science, and the Kavli Foundation, as well as patient advocacy organizations and universities have committed over \$240 million to The BRAIN Initiative. In addition, members of the National Photonics Initiative and other companies such as GE, GlaxoSmithKline and Inscopix have joined this effort through commitments of more than \$30 million in research and development investments. There is much work to be done and opportunities for others to play a role in this historic initiative through new and expanded commitments.

The President's 2016 Budget proposes to increase the Federal investment in The BRAIN Initiative from about \$200 million in FY 2015 to more than \$300 million in FY 2016. Proposed investments by the NIH, DARPA, IARPA, FDA and NSF are described below.

National Institutes of Health (NIH): In FY 2016, NIH will provide an estimated \$135 million in funding for The BRAIN Initiative. This investment will support a diverse set of projects with ambitious goals, including developing new devices to record and modulate activity in the human nervous system, revolutionizing human neuroimaging technologies to understand how individual cells and complex neural circuits interact in time and space, and modeling and analyzing the complex data that scientists obtain in their quest to understand how the brain works. Together these research efforts aim to develop and apply cutting-edge technologies to create a dynamic picture of the brain in action, providing the critical knowledge base for researchers seeking new ways to treat, cure, and even prevent brain disorders.

A working group of the Advisory Committee to the NIH Director was established to inform planning for The BRAIN Initiative at the NIH, and this group sought broad input from the scientific community, patient advocates, and the general public. In June 2014 the group released a report entitled *BRAIN 2025: A Scientific Vision*, which articulates the scientific goals of The BRAIN Initiative at the NIH and charts a multi-year scientific plan for achieving these goals, including timetables, milestones, and cost estimates. Additionally, NIH has established a BRAIN Multi-Council Working Group of esteemed experts in numerous disciplines who assist in ensuring a coordinated and focused effort across the agency. NIH is also working in close collaboration with other government agencies and private partners to ensure success through investment in The BRAIN Initiative. In FY 2014 NIH issued 58 awards to develop a variety of new technologies and approaches to understand the brain. These projects include a systematic inventory of the brain's different cell types, approaches for accessing specific cells and circuits, new capabilities for simultaneously recording activity across large groups of neurons, next generation methods for imaging human brains, and interdisciplinary approaches to understanding how brain circuits produce unique brain functions. For FY 2015 and beyond, NIH will issue new awards aiming to build on these initial projects to develop devices to monitor and modulate human neural activity for understanding brain function and treating brain disorders. Informed by an NIH workshop on ethical issues in neuroscience research, NIH will also engage investigators to explore important neuro-ethical issues in modern brain science

Defense Advanced Research Projects Agency (DARPA): In FY 2016, DARPA plans to invest an estimated \$95 million to support The BRAIN Initiative. DARPA's investments aim to leverage brainfunction research to alleviate the burden of illness and injury and provide novel, neurotechnology-based capabilities for military personnel and civilians alike. In addition, DARPA is working to improve researchers' abilities to understand the brain by fostering advancements in data handling, imaging, and advanced analytics.

In FY 2016, the Restoring Active Memory (RAM) effort will be conducting its first human clinical trials to identify how memories are encoded in the brain during learning and skill acquisition, with the ultimate goal of accelerating warfighter recovery after traumatic brain injury. DARPA's neuro-adaptive technology program, Systems-Based Neurotechnology for Emerging Therapies (SUBNETS), aims to demonstrate the first set of prototype closed-loop medical devices able to measure and modulate networks of neurons in research participants with intractable psychiatric illness and alleviate severe symptoms of diseases such as post-traumatic stress disorder and major depression. DARPA's neuroscience technologies programs have already begun to analyze large datasets of neural signals, allowing investigators to rapidly and transparently solve complex problems of computation, generate new models, and model the brain in multiple dimensions and spatiotemporal scales. In 2016, initial datasets generated through DARPA's programs will be made available for secondary research. New efforts in the Neuro-Function, Activity, Structure, and Technology (Neuro-FAST) program will be testing how new imaging discovery tools using optical and photonic techniques are capable of sensing the structure and activity of thousands of neurons simultaneously in the active brain. Such high resolution in a stable manner over multiple experiments promise new insights into brain function and clues to treat injury. The Hand Proprioception and Touch Interfaces (HAPTIX) effort will develop human-ready implantable electronic microsystems that interact with sensory and motor peripheral nerves, with the goal of enabling amputees to feel with their prosthetic limb through sensory feedback as well as achieve advanced and intuitive limb control. In 2016, HAPTIX users will test a fully implantable wireless recording device, as well as begin the first take-home trial of their prosthetic hand. Finally, the Electrical Prescriptions (ElectRx) program seeks to understand and leverage the function of peripheral nerve and spinal cord neural circuits to advance neuromodulation therapies for immunological and mental health disorders. Parallel investments in physiological research and technology development will yield more complete understanding of the neural circuits involved in regulating health.

National Science Foundation (NSF): In FY 2016, NSF plans to invest \$72 million to support The BRAIN Initiative. To attain a fundamental scientific understanding of the complexity of the brain, in context and in action, NSF investments in The BRAIN Initiative are focused on generating an array of physical and conceptual tools needed to determine how healthy brains function over the lifespan of an organism, including humans. NSF will also focus on the development and use of these tools to produce a comprehensive understanding of how thoughts, memories, and actions emerge from the dynamic actions of the brain. NSF is prioritizing research in three areas where the agency's capacities are uniquely strong: integrative and interdisciplinary research; new theories, computational models, and analytical tools that will guide research questions and synthesize experimental data; and the development of innovative technologies

and data infrastructure required to handle the large-scale datasets resulting from this research. Examples of investments that NSF has already made to support The BRAIN Initiative include a new \$25 million Science and Technology Center on "Brains, Minds and Machines" at the Massachusetts Institute of Technology, 36 awarded Early Concept Grants for Exploratory Research directed at identifying the emergent properties of neural circuits that underlie behavior, and new Research Coordination Networks (RCNs) to organize the scientific community and increase collaboration. In FY 2016 NSF will begin to discuss and coordinate plans for the potential creation of a National Brain Observatory with other agencies and the National Laboratory Network.

Intelligence Advanced Research Projects Activity (IARPA): In FY16, IARPA plans to invest in at least three research programs in applied neuroscience to advance our understanding of cognition and computation in the brain. The Strengthening Human Adaptive Reasoning and Problem-solving (SHARP) program will test and validate non-invasive neural interventions that have the potential to significantly improve adaptive reasoning and problem-solving, ultimately leading to improvements in human performance in information-rich environments. The Knowledge Representation in Neural Systems (KRNS) program will seek insights into the brain's representation of conceptual knowledge as a step toward building new analysis tools that acquire, organize, and wield knowledge with unprecedented proficiency. Finally, the Machine Intelligence from Cortical Networks (MICrONS) program will begin to reverse-engineer the algorithms of the brain to motivate the design of novel, neurally-derived machine learning algorithms that can perform complex information processing tasks.

Food and Drug Administration (FDA): In FY 2016, FDA plans to continue to support The BRAIN Initiative by enhancing the transparency and predictability of the regulatory landscape for neurological devices and assisting developers and innovators of medical devices, which is so critical to realizing the investments made by our federal, and private sector partners. Moving forward, FDA's Center for Devices and Radiological Health has proposed a new voluntary program for certain medical devices, including devices applicable to The BRAIN Initiative, that demonstrate the potential to address unmet medical needs for life threatening or irreversibly debilitating diseases or conditions. This new program would provide an expedited pathway to market for qualified devices. FDA will continue to take actions to improve the efficiency, consistency, and predictability of clinical studies for investigational medical devices in general, and for devices of public health importance, in particular, under the Clinical Trials Enterprise Initiative.¹ FDA will continue to engage stakeholders to assist developers and innovators in moving safe and effective products to the market. FDA remains committed to continuing its role under The BRAIN Initiative in making as transparent as possible the regulatory framework applicable to neurological devices and thereby helping to bring safe and effective products to patients and consumers.

¹http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM384576.pdf