Agency Assessment of Ethical, Legal, and Societal Implications of Neuroscience and Technology Research and Its Relationship to the Presidential BRAIN Initiative

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For My Family

My husband Arif, and my children, Eliza and Zaid
without whom this would not have been possible
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ABSTRACT

In this study, I examined the societal views for neuroscience and technology research (neuro S&T), as reflected through interviews conducted with agency personnel and researchers. Thus, the aim of the study was to address the ethical and legal questions surrounding neuro S&T research by interviewing agency leaders and the scientific community, reviewing data from public surveys, and analyzing research and development funding allocations (specific to the BRAIN initiative), in order to better understand the influence of Presidential initiatives on agencies, the resulting science and technology outputs, and the effect these have on the general public.

Consequently, this study was divided into three parts, (I) agency and researcher interview, (II) review of public survey data on neuro S&T, and (III) archival analysis of research and development funding specific to the BRAIN initiative for FY 2014, 2015 and 2016. The two programs chosen from NIH were (1) Next Generation Human Imaging and (2) Next Generation Human Invasive Devices. The two programs chosen from DARPA were (1) Hand Proprioception and Touch Interfaces (HAPTIX) and (2) Electrical Prescriptions (ElectRx).

Through collection and analysis of the data in this study, our findings were able to address the central research question of this study, of how agencies that follow the Presidential BRAIN initiative address ethical, legal and societal views on neuro S&T research. Both agencies, DARPA and NIH, utilize internal and external mechanisms to control for potential risks associated with the funded research. The external boards, such as the ELSI panel used by DARPA and the NWG panel used by NIH, have members that are experts in all fields of neuroscience, as well as outside experts that provide a worldview of society and the impacts of these technologies. There are several different levels of oversight and internal and external review of all aspects of the research study. These mechanisms ensure all research is conducted
with the highest ethical standards and minimizes all risks associated with the research. Researchers and agency personnel incorporate the recommendations from these experts in their programs to ensure safe distribution and use by the public upon release of these technologies.

At the beginning of this study, we chose to explore how DARPA and NIH, two agencies that are so vastly different in their mission, vision, and structure along with Federal alignment (which changes the policies and guidelines they have to adhere to for ethical and legal issues; DARPA/DoD and NIH/DHHS), choose to participate in the BRAIN initiative. Through analysis of the data ($H_1$), we saw that choosing to participate in the BRAIN initiative aligned with DARPA’s and NIH’s structure, mission, and vision. While we deduced, the responses should be very different due to the two agencies being completely different from each other, it seems in following the BRAIN initiative funding for extramural research, specifically neuro S&T research that can be translated into public use, DARPA and NIH follow a very similar path. However, $H_1$ was rejected, due to the responses gathered after change in the Presidential administration. The responses showed no change in how agencies were participating or funding the BRAIN initiative. Therefore, it was concluded that based on data gathered to date, Presidential administration does not influence an agencies participation in an initiative.

Through analysis of the interviews by the agency personnel and researchers ($H_2$), we were able to see how agencies and researchers, find and resolve ethical and legal issues surrounding neuro S&T research, and weigh them based on the needs of the society. They use internal and external subject matter experts, cost-benefit analysis, risk-reducing strategies, oversight of data safety monitoring boards, and IRBs to ensure work occurs with the highest ethical standards. We saw that agencies and researchers are utilizing both internal and external aid to figure out and address all possible issues relating to neuro S&T. Public outreach programs
to include open call meetings and webinars are being held by Neuroethics groups. These outreach programs through agencies have potential to influence the outlook of the public and decrease their apprehension on the use of these technologies.

Communication between stakeholders and timely addressing of issues (such as continual access to treatment and care, post-trial obligations, responsible conduct, etc.) through policies, can lead to an increase in the public trust in these technologies. This study made it clear that agencies and researchers are very cautious about funding neuro S&T research. They have set up several checks and balances within agencies and research institutes to ensure all funded research occurs with the highest ethical and legal standards and increases the positive societal impact of these technologies. Since most of these devices are currently in their novice stages of development, their full impact on society will not be known until full deployment into society. Therefore, careful consideration into policies that address and place emphasis on the “human values” will ensure a positive impact on the society, as well as implementing Presidential initiatives.
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KEY TERMS AND CONCEPTS

Deep Brain Stimulation: small electric shocks are delivered to a specific part of the brain with surgical intervention to treat patients with certain disorders (for example, depression).

Diffusion Tensor Imaging (DTI): used to characterize the three-dimensional diffusion of water as a function of spatial location.

Electroencephalography (EEG): a noninvasive monitoring method to record the electrical activity of the brain.

Functional magnetic resonance imaging (fMRI): measures brain activity based on changes in blood flow.

Neuromodulation: process by which a given neuron uses chemicals to regulate other groups of neurons.

Neuroplasticity: the brain’s ability to form new neural connections to compensate for injury or disease and adjustment in activities in response to changes in the environment.

Neurotechnology Research: to create technologies to assist in repairing or restoring brain function; also to create technologies that imitate brain function.

Peripheral nervous system: the nervous system outside the brain and spinal cord, with sensory neurons and connector neurons that form the communication network between the central nervous system and the body parts.

Positron Emission Tomography (PET): a functional imaging technique to observe metabolic processes in the brain by radioactively labeled metabolically active chemicals.

Public Policy: a policy response to public problems; for the purposes of this research, it will be limited to policies impacting neuroscience and technology research.

Stakeholders: those affected by a policy; for the purposes of this research, we will focus on those individuals which are directly impacted and involved with the BRAIN initiative.

Shareholders: those that hold stock of a company and have potential to benefit when the company profits.

The Common Rule: also known as 45CFR46. All federally funded agencies have to abide by the regulations in the common rule when conducting human subjects research. When humans are part of a federally funded study in any way, the research being conducted has to be held up by the ethical standards set forth in the common rule.

Transcranial Direct Current Stimulation: constant low current is delivered to the brain via electrodes on the scalp to assist patients with brain injuries (for example, stroke patients).

Transcranial Magnetic Stimulation: a noninvasive procedure that utilizes magnetic fields to stimulate nerve cells in the brain to treat patients (for example, depression).

Translational Neuroscience: process of using all technological advances to bring novel therapies with measurable outcomes to patients with neurological diseases.
CHAPTER 1
INTRODUCTION

Intent of the Study

In this study, I critically examined the ethical, legal and societal views of specific neuroscience and technology research programs (neuro S&T) as reflected through interviews conducted with agency personnel and researchers. Thus, the aim of this study was to address the ethical and legal questions surrounding neuro S&T research by interviewing agency leaders and the scientific community, reviewing data from public surveys, and analyzing research and development funding allocations (specific to the BRAIN initiative), in order to better understand the influence of Presidential initiatives on agencies, the resulting product, and the effect it has on the general public. The central research question of this study is how agencies that follow the Presidential BRAIN initiative address ethical, legal and societal views on neuro S&T research. The central research question gave rise to the following interrelated hypotheses of this study generated largely from the scientific, policy, legal, and public opinion literature:

- **H1**: If an agency’s leadership is a Presidential appointee, and a Presidential Initiative falls within their mission, then the agency is pressured to focus their work to align with the initiative.
- **H2**: If societal needs outweigh the ethical and legal risks associated with a particular neuroscience and technology research project, then the research will be funded by an agency, contingent upon a mitigation strategy.

Consequently, this study was divided into three interrelated parts: (I) agency and research professional interviews, (II) review of public survey data on neuro S&T, and (III) archival
analysis of research and development funding specific to the BRAIN initiative for FY 2014, 2015, and 2016.

Statement of the Problem

On July 17, 1990, President George H. W. Bush declared that key federal investments were to be made during the decade, 1990-2000, to focus research on neuroscience, through proclamation 6158 (“Presidential Proclamation 6158.” 1990). From then to 2013, when President Obama announced the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) initiative, countless efforts have been undertaken by researchers in both the public and private sector to make advances in neuro S&T. Although there has been substantial and diverse funding and agency involvement and support for public policies in neuro S&T research in the past twenty-six years, the ultimate success and utility of neuro S&T for the public depends upon continued and expanded public support by acceptance of its research outcomes.

Rationale for the Study

In 2013, President Obama announced the BRAIN initiative, through the Office of Management and Budget (OMB) in the United States (“Fact Sheet: BRAIN initiative.” 2013). Similar to what the human genome project did for DNA mapping, the BRAIN initiative is supposed to develop technologies and subsequent application of those technologies in facilitating the understanding of the brain’s functions. Some of the goals include unraveling complex brain disorders, such as traumatic brain injury, Parkinson’s disease, Alzheimer’s disease, depression, and other disorders (Sargent 2013). In the U.S., adults with mental health problems constitute 43.8 million of our current population, per statistics from the National Institute of Mental Health (Substance Abuse and Mental Health Services Administration 2013). Therefore, finding
solutions for this growing problem is an important task. Through this initiative, researchers will focus on translational neuroscience as one of the main tasks in order to address the growing population of individuals with mental health conditions, wherein translational neuroscience is defined as the process of using all technological advances to bring novel therapies with measurable outcomes to patients with neurological diseases.

The U.S. government dedicated approximately $100 million in funding for FY 2014 and approximately $200 million in FY 2015 (Sargent 2015). Table 1 (below) shows the budget allocations that went to the agencies that answered the President’s call. These funds are to be used specifically for the BRAIN initiative, as stated by the OMB (Hourihan and Parkes 2015). The initiative encourages agencies in both the public and private sector to assist in developing tools and transforming our understanding of the brain. In the public sector, the Defense Advanced Research Projects Agency (DARPA), National Science Foundation (NSF) and the National Institute of Health (NIH) have already awarded several grants and solicitations in relation to the BRAIN initiative. In the private sector, the Allen Institute for Brain Science, Howard Hughes Medical Institute, the Kavli Foundation, and others are carrying this initiative forward.

Table 1. BRAIN initiative Funding Allocations per Agency for FY 2014, 2015, and 2016 (Per Research and Development budget allocations from OMB in million dollars).

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<tr>
<th>Agency</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
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<tr>
<td>DARPA</td>
<td>38</td>
<td>80</td>
<td>95</td>
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<td>NIH</td>
<td>40</td>
<td>100</td>
<td>135</td>
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<td>NSF</td>
<td>23</td>
<td>48</td>
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The Public Sector

NIH is granting awards to internal scientists and external contractors that focus on developing new techniques and tools to understand the brain. Some of the current awards focus on:

(1) Classifying the different cell types in the brain.
(2) Producing technologies and analyzing brain circuits and cells.
(3) Incorporating theories of the brain with experiments to better understand the circuits in the brain.

A panel convened by NIH projected that the agency needs approximately $4.5 billion over the course of the next 12 years to successfully carry out the goals stated in their “BRAIN 2025: A Scientific Vision” plan (“BRAIN 2025: A Scientific Vision.” 2014). Since NIH’s mission is to enhance health and reduce illness, focusing their work on the health-related translational neuroscience facilitates the accomplishment of their mandated goals.

Simultaneously, NSF is focusing on fundamental research and development of neurotechnology. Some of the current awards focus on:

(1) Understanding the structure of the brain.
(2) Neurotechnology and research infrastructure.
(3) Modeling of brain function.

The research funded by NSF in support of the BRAIN initiative will implement its mission of supporting basic scientific research as stated in the National Science and Foundation Act (1950); and the 2011-2016, vision of “capitalizing on new concepts in science and engineering and provide global leadership in advancing research and education” (“NSF Mission and Vision.” 2014).
DARPA is focusing on translational neuroscience research. Some of the current awards focus on:

(1) Therapies directed towards patients with psychiatric and neurological disorders.

(2) Focusing on restoring memory following traumatic brain injury or any other neurological disease/disorder.

(3) Seeking to better understand neuron activity and neural structures.

DARPA’s mission is to utilize strategies that enable a fast, efficient, work environment to produce high-quality products to aid the warfighter and civilians. In moving forward with the BRAIN initiative, the DARPA Director stated that the agency should focus on analyzing “electric signals and the biomolecular dynamics behind brain function” (“Better Understanding of Human Brain Supports National Security.” 2013).

**The Private Sector Participation and Mandates in the Brain Initiative**

There are three key private sector partners that helped launch the BRAIN initiative and made immense progress in their commitments:

The Allen Institute for Brain Science- a nonprofit medical research organization located in Washington; completed the Allen Mouse Brain Connectivity Atlas. In 2014, the Allen Institute partnered with Google to develop complex and dynamic computational tools to aid in our understanding of the brain.

The Howard Hughes Medical Institute located in Maryland- invested over $70 million to support the initiative and is developing tools and technologies to understand how neural networks function in the brain.

The Kavli Foundation located in California- focusing on innovative brain research, has established two new neuroscience institutes to advance its worldwide network of Kavli
institutes; established “Neurodata Without Borders” a program that promotes data sharing among scientists specific to the neuroscience discipline.

Prior to the U.S. government’s initiation of the BRAIN initiative, the European Union had already been allocating funds for the Human Brain Project (HBP). The HBP involves partner institutes in approximately 26 countries and has a total cost estimate of 1.19 billion euros over a period of 10 years. The HBP is developing the first draft model of the rodent and human brain within the first 10 years of funding. The funding obligations are used toward several foci:

(1) Neuroinformatics

(2) Brain simulation

(3) High-performance computing

(4) Medical informatics

(5) Neuromorphic computing

(6) Neurorobotics

It was not initially pitched as a neuroscience project; but rather a future technology project funded by dollars associated with information and communication technologies. Researchers were to focus on cutting edge ICT platform for brain research, brain inspired computing, artificial intelligence, neuro-robotics, etc. It was not just a project aimed at modeling the brain. Ethics and society group as part of the HBP project, promotes engagement with decisions makers, public, and stakeholders (+Horizon 2020 programs). Ethics Advisory Board (independent body of advisors) works with the two ethics-focused groups (in the sub-group). The purpose of the group is to:

- Raise social and ethical awareness among the scientists
- Ensure compliance with legal and ethical norms
• Ensure all social, ethical, and legal issues are taken up and covered by the project.

In this research study, I will choose two programs from DARPA and NIH that focus on translational neuroscience, as those have the most impact on the public when released for use. Both NIH and DARPA have Directors that are Presidential appointees. Most of the directors are changed or replaced when new administration takes office, as every Presidential administration has their own mission and vision that they want the agencies to focus on. However, DARPA and NIH as agencies have different missions. DARPA’s mission is to utilize strategies that enable a fast, efficient, work environment to produce high-quality products to aid the warfighter and civilians. However, NIH’s mission is to enhance health and reduce illness; focusing their work on the health-related translational neuroscience facilitates the accomplishment of their mandated goals. DARPA’s focus is more technology based, while NIH’s mission is geared towards health advances. Therefore, comparing and contrasting how both Presidentially appointed Director agencies take on a Presidential initiative, and what ethical, legal, and societal implications the development and approval of these neuroscience technologies gives rise to, particularly for public policy and administration. It is important to note that the issue of “societal barriers” is not support for funding but acceptance of research outcomes by the general public. To summarize the currently some of the ethical, legal and societal issues are:

Ethical- autonomy, freedom, fairness, and safety for the public, which generates concerns for informed consent, equity among all groups and minimization of risk for all.

Legal- justice and fairness. As these issues give rise to problems of using brain technologies to make assumptions about defendant behavior. Utilization of neuro S&T should not inhibit the right to obtain a fair trial that is free of judgement by all.
Social-justice in the distribution of the existing and potential goods and services generated by neuro S&T research. Leading us to our overall concerns with access and quality of health care, fair distribution of treatment and new technologies beyond giving health care advantage to some over others.

The programs at DARPA and NIH will give insight into the societal and ethical impact of neuro S&T research. Although there has been substantial and diverse funding, agency involvement, and supportive public policies in neuro S&T research in the past twenty-six years, the ultimate success and utility of this work for the public depends upon continued and expanded public support.

Public support requires three steps:

First, the public must know.
Second, they must interact with agency and researchers.
Third, they must comprehend.
Fourth, they must decide to support or not to support the research.

As the public makes this decision, they will articulate their ethical, scientific or other rationale for the decision. So, aside from identifying “societal views,” the real core contribution of this research study is to identify the strategies of the agencies involved. After this is accomplished, the scientific community can begin to address these “views” and the public policy driving and resulting from these strategies.

For the purpose of this study, programs that focused on translational neuroscience were chosen from DARPA and NIH. In this study, translational neuroscience is being used as, a process of using all technological advances to bring novel therapies with measurable outcomes to patients with neurological diseases. Two programs from each agency were selected:
(1) Next Generation Human Imaging- The purpose of this program is to award researchers with funding that focuses on three areas: (1) Precise Interventional Tools: link brain activity to behavior through development of next generation tools that first will be tested in animal and then humans focusing on optogenetics, chemogenetics, and biochemical and electromagnetic modulation (“BRAIN 2025: A Scientific Vision.” 2014). (2) Advance Human Neuroscience: understand and to treat the human brain through development of innovative technologies. (3) Techniques to Monitor Neural Activity: monitor the human brain through establishment of methods to conduct large scale monitoring of neural activity.

Researchers at Vanderbilt University, Massachusetts Institute of Technology, University of Arizona, Yale University, University of Minnesota, and University of California are among those that have been awarded funds under this program.

(2) Next Generation Human Invasive Devices- The purpose of this program is to award researchers with funding that focuses on three areas: (1) Precise Interventional Tools: link brain activity to behavior through development of next generation tools that first will be tested in animal and then humans focusing on optogenetics, chemogenetics, and biochemical and electromagnetic modulation (“BRAIN 2025: A Scientific Vision.” 2014). (2) Advance Human Neuroscience: understand and to treat the human brain through development of innovative technologies. (3) Techniques to Monitor Neural Activity: monitor the human brain through establishment of methods to conduct large scale monitoring of neural activity.
Researchers at Massachusetts General Hospital, Baylor School of Medicine, Emory University, Cleveland Clinic, Mayo Clinic, and Weill Medical College of Cornell University are among those that have been awarded funds under this program.

DARPA

(1) Hand Proprioception and Touch Interfaces (HAPTIX)- The purpose of the program is to award researchers with funding in the areas which will enable/create a prosthetic hand system that moves and feels like a natural human hand. The goal is to make the users of the prosthetic hand get the same type of “natural” feeling someone gets without a prosthetic arm.

Researchers at Cleveland Clinic, Case Western Reserve University, Draper Laboratory, University of Pittsburgh, University of Utah, and University of Florida are among those that have been awarded funds under this program.

(2) Electrical Prescriptions (ElectRx)– the purpose of the program is to award researchers with funding in the areas which will enable/create ways to modulate the peripheral nervous system to fight diseases. The program envisions to treat conditions such as post-traumatic stress disorder, inflammatory diseases, depression, and chronic pain in different parts of the body. Technologies created through this program should be able to detect onset of disease and automatically restore health in an individual by stimulating the corresponding part of the peripheral nerves as needed.

Researchers at Columbia University, Circuit Therapeutics, Florey Institute of Neuroscience and Mental Health, Johns Hopkins University, Massachusetts Institute of Technology, Purdue University and University of Texas are among those that have been awarded funds under this program.
This chapter has established, the overall intent and rationale for this study through the articulation of the issues being addressed by the two agencies and the executive branch. Therefore, Interviews with the researchers and agency personnel associated with these programs, are designed to help determine the nature of societal views on these neuro S&T research efforts and how they are being addressed by the agencies and researchers. This chapter, provided a preview of the dynamics of the methodology, which will be established through the literature review in the next chapter.
CHAPTER 2
LITERATURE REVIEW

The purpose of this literature review is to examine the ethical, legal, and societal views that surround neuro S&T research as reflected in the literature. Among the dilemmas that emerge in each discipline will influence the research methodology and design of this study. In addition, the themes that emerge will assist in developing questions for interviewing agency leaders and the scientific community on neuro S&T research, as well as developing the hypotheses for this study.

Background

According to Presidential Proclamation 6158, on July 17, 1990, President George H. W. Bush declared that key federal investments were to be made during the decade 1990-2000 to focus research on neuroscience, through proclamation 6158 (“Presidential Proclamation 6158.” 1990), which subsequently established the Decade of the Brain. The initiative involved the National Institute of Mental Health (NIMH) of the NIH and served to advance a number of key research initiatives and findings in brain research, with a focus on understanding brain diseases. The presidential proclamation articulated the goals and objectives of the strategy and delegated initial administrative responsibility for its implementation to NIMH.

Using the Decade of the Brain’s research as a starting point, the Decade of the Mind manifesto was drafted by a group of scientists from the Sandia National Laboratory and other, non-governmental institutions in May 2007 (Olds 2011). This was an initiative established by the United States government and proposed and run by U.S. scientists to bring awareness to complexities of the brain and to propose a plan to move forward. The scientists, projected a ten-year plan to devote approximately $4 billion in federal funds to initiate research in different areas
from computer science to neuroscience focusing upon neural bases of cognition and behavior, and to enable bio-engineering approaches to model neuro-cognitive functions. Subsequent Decade of the Mind conferences were held in 2008, 2009, and 2010, involving the United States, Europe, and Asia, resulting in this U.S. initiative becoming an international initiative (Olds 2011). Despite promising results from these meetings (on the science and technology regarding neuroscience), due to the harsh global economic environment, countries were not able to allocate sufficient research and development funding towards this work.

**Presidential Leadership and the BRAIN Initiative**

Over the years the President’s role has evolved into one where the President has taken center stage in the government (Edwards and Wayne 2013, 15). However, one of the paradoxes of the President’s position is that the public doesn’t want a very strong or a very weak President (Cronin and Genovese 2012, 5). The President in his leadership role has to walk a very fine line when making policy decisions. While, the President has the power and influence to pass proclamations and initiatives to influence change in areas where they see fit. The President is still held accountable for the decisions that he makes during his administration (Cronin and Genovese 2012, 122). With the BRAIN initiative, President George H. W. Bush declared that key federal investments were to be made during the decade 1990-2000 to focus research on neuroscience, through proclamation 6158 (“Presidential Proclamation 6158.” 1990), thus establishing the Decade of the Brain. In 2013, President Obama, taking neuro S&T research, one step further, announced the BRAIN initiative, through OMB (“Fact Sheet: BRAIN initiative.” 2013). Neustadt (1991), explains how Presidents can use their powers to make a change. In the case of the BRAIN initiative these President’s used their influence to take a cause, which they thought needed more attention and research and development one step further (Neustadt 1991, 6).
Presidential Initiatives are formed through a set of features, as reflected in series of documents reviewed. According to Olds (2011), the first feature, “a critical piece,” is that the scientific community, that means scientists in industry and academia, in agencies, students, senior scientists, people who fund research outside of the government like foundations and philanthropists, clearly articulated a need for something to happen that is not currently happening. In the BRAIN Initiative, a set of scientists (neuroscientists, engineers, nanoscientists, etc.) got together and said that right now there are a bunch of questions that we want to ask about the brain that we cannot ask and cannot answer because we don't have the tools to ask and answer those questions (Olds 2011). However, currently there is not a vision for how the development of those tools is going to happen. Also, it was not obvious to anyone, or apparent to anyone at the time, that there was any kind of funding source, federal agency or not, that was going to fully fund the development of this tool (Alivisatos et al. 2012).

The review of these documents showed that there was a need and there was not a clear individual actor who could satisfy that need. The group of scientists wrote a paper in the journal Neuron, titled “Brain Activity Map” in 2012. Publication of that paper got the attention of senior personnel at agencies, from several nonprofit foundations and private research institutes as well. At that point DARPA, NIH, and NSF, all joined in and said, we should all work together to get this started. At that point, Office of Science and Technology Policy (OSTP), took the project to the President and got his approval to move it forward as an initiative.

In 2013, President Obama announced the BRAIN initiative, through OMB (“Fact Sheet: BRAIN initiative.” 2013). In working with the OMB, it was a part of the President's budget request for fiscal year 2014. Based on the need as stated in the reports published by the scientists and subject matter experts, the focus of the BRAIN initiative is intended to develop technologies
and subsequent application of those technologies in facilitating the understanding of the brain’s function. Some of the goals include unraveling complex brain disorders, such as traumatic brain injury, Parkinson’s disease, Alzheimer’s disease, and depression (Alivisatos et al. 2015).

Researchers will be focusing on translational neuroscience, as one of the main tasks to undertake through funding allocated under this initiative. Next, we will look at what the agencies have to do to obtain the funding.

**Funding Request and Appropriations**

According to OMB Circular A-11, to obtain federal funding, agencies develop their proposals, what they want to spend money on for the coming year (one year out). They send those proposals to the Office of Management and Budget (OMB) in the White House, and the OMB works through agency and department proposals for the entire federal government (Heniff et al. 2012). Then the policy councils in the White House, like OSTP, National Economic Council, National Security Council, Domestic Policy Council, etc., work with the agency leadership and OMB to make sure that the administration's priorities are reflected in the agency and department-specific budget proposals.

OMB Circular A-11, makes clear the role of budget examiners. The budget examiners work specifically on agencies and sometimes specific institutes within an agency. For example, in NIH’s annual budget request, there are people in OSTP that work with them, but that also ends up being a piece of the entire Department of Health and Human Services budget request, and there are many other agencies that are part of that as well (Heniff et al. 2012). OMB provides the organizing of the budget requests in the White House. Ultimately, all the details get litigated. Sometimes agencies get everything they ask for, sometimes they get part of what they ask for, and it is all part of the negotiation process. Everything from OMB, the agencies, and examiners
gets compiled into a single document that ends up being the President's budget request (Heniff et al. 2012). All of this takes place in the Executive branch of the government. The Executive branch has no authority to give out funding; therefore, the President sends the request to Congress.

Usually, the President sends that budget request to Congress in the winter or early spring. Congress takes that Budget Request, and the Appropriations Committee, in both the House and the Senate, reviews the budget request and deliberates on how much to allocate to whom (Saturno 2011). At that point, Congress appropriates the funds. So, the appropriations bills are the ones that say how much the funds are and which agency is getting funded. In a functioning environment in Washington DC, those appropriations bills are relatively similar to what the President has asked for, for each of the departments and agencies. And in the cases where they are not, it is clearly articulated by Congress why some agencies or departments are getting less money and why some are getting more money. This process sets the spending for the federal government (Saturno 2011). Usually this process starts when the President sends the budget over in March. Then Congress has from March until the end of September to pass appropriations bills, and the fiscal year starts on October 1st. Figure 1, provides a complete overview of the budget process, as deduced by review of all federal budgetary documents by OMB and the federal agencies.
In 2013, President Obama announced the BRAIN initiative through OMB (“Fact Sheet: BRAIN initiative.” 2013). It was a part of the President's budget request for fiscal year 2014. A review of the key elements from the President’s Initiative, show that the BRAIN initiative is intended to develop technologies and subsequent application of those technologies in facilitating the understanding of the brain’s function. Some of the goals include unraveling complex brain disorders, such as traumatic brain injury, Parkinson’s disease, Alzheimer’s disease, and depression. Researchers will be focusing on translational neuroscience, as one of the main tasks to undertake through funding allocated under this initiative. The process listed above from the beginning of the initiative to disbursement of funds for research is the process the agencies had to follow to obtain funding under the BRAIN initiative.

From then to 2013, when President Obama announced the BRAIN initiative, countless efforts have been undertaken by researchers in both the public and private sector to make advances in neuro S&T. Although there has been substantial and diverse funding, agency involvement, and support for public policies in neuro S&T research in the past twenty-six years, the ultimate success and utility of neuro S&T for the public depends upon continued and
expanded public support by acceptance of its research outcomes (“Fact Sheet: BRAIN initiative.” 2013).

Therefore, in this study, I compare and contrast how DARPA and NIH, agencies that have Presidential appointments of Directors, decided to participate in the BRAIN initiative; and what ethical, legal, and societal views the development and approval of the technologies being funded through the BRAIN initiative give rise to and its impact on public policy. It is important to note that the issue of “societal views” is not the support of funding by the general public, but is the acceptance of research outcomes by the general public.

**DARPA**

The Strategic Plan for the Defense Advanced Research Projects Agency (DARPA) outlines, that President Eisenhower wanted a dedicated agency in the United States that would help the U.S. gain technological advancement over its adversaries. Thus, DARPA was established in 1958. The development of the agency was in response to the Sputnik launch in 1957 by the Soviet Union. President Eisenhower wanted the establishment of an agency that would ensure that the U.S. created military technology that would be more advanced than its adversaries. DARPA’s original mission was to “prevent technological surprise” (From mission, management, and organization (2.1) provided in the Strategic Plan, May 2009 by the Defense Advanced Research Projects Agency); over time, this mission has evolved. DARPA’s current mission is to “prevent technological surprise for us and to create technological surprises for our adversaries” (“Breakthrough Technologies for National Security.” 2015). To reach its mission, DARPA utilizes strategies that enable a fast, efficient, work environment to produce high-quality products to aid the warfighter. DARPA hires the best and brightest in the field, from all over the world, to aid in fulfilling its mission. DARPA’s vision is to foresee “what capabilities a future
military commander might need and accelerate those capabilities into being through technology

As stated in the DARPA Strategic Plan, the DARPA Director is a Presidential appointee
with a 4-year term. DARPA Director, program managers, and research teams work directly with
warfighters, commanders, and leaders of Army, Navy, Marine Corps, and Air Force to seek their
advice on what they need in and out of theatre, to obtain an edge over our adversaries. DARPA
currently has approximately 240 employees (“Breakthrough Technologies for National
Security.” 2015). The program managers at DARPA are hired for a 4-year term, at the end of
which their research programs are handed over to a new program manager. Thus, research
funded by DARPA is conducted at a fast pace within a short time frame, to produce results
through technologies that can be translated into public use. Research funded by DARPA is
conducted to fulfill the primary goal and objective of “radical innovation” (“Breakthrough
Technologies for National Security.” 2015). The mission, goal, and vision of DARPA along
with the internal and external stakeholders’ input is what shapes DARPA’s strategic plan.
DARPA was created to aid all departments in the Department of Defense (DoD) in establishing
technological advancements. The President, (through the budget allocations), the Secretary of
Defense, and leaders within the DoD all influence the main areas where DARPA focuses its

Currently, there are five mandates being funded at DARPA. These mandates were
formed through legislative tasking and by request of external stakeholders. First, to produce
robust, secure, and self-forming networks; this will aid the U.S. in turning information
superiority into combat power. Second, influenced by the ever-changing external environment
and threats around us, urban area operations; where the mission is to seek new urban warfare
concepts and technologies. Third, advanced manned and unmanned systems; where we have been tasked by our external stakeholders, to establish a battlefield with network manned and unmanned air, ground and marine systems. Fourth, with an increase in bunkers, and unground caves being utilized as hiding spaces by our adversaries, detection, characterization and assessment of underground structures has become very important; therefore, we are focusing on developing ground and airborne sensor systems. Fifth, the main reason DARPA was initially created, space: maintaining unhindered U.S. access to space and protect U.S. space capabilities from attack. While there are many other unspoken and written mandates, these mandates from 2009 to DARPA’s current management plan are all relevant and being readily funded every year (“Breakthrough Technologies for National Security.” 2015).

Therefore, in 2013, when the President signed the BRAIN initiative, DARPA was already working on some neuro S&T research projects, but announced how they planned to take the President’s initiative to the next level. As an agency, they dedicated $38 million towards just the BRAIN initiative. As published in the Computing Community Consortium Catalyst (Underwood. 2013), DARPA for FY 2014 announced its first, two programs funded as part of the BRAIN initiative, SUBNETS (Systems-Based Neurotechnology for Emerging Therapies and RAM (Restoring Active Memory). SUBNETS was established to develop technology that treated mental health issues. Mental health illnesses are hard to understand and the number of individuals affected by them is increasing exponentially. It is important for researchers to focus on these treatments and provide care for individuals that need it. The goal of this program was just that, as the solicitation for the program stated:

“DARPA seeks to develop a new understanding of complex, systems-based disorders of the brain. A major goal of this effort is to deliver a platform technology for precise therapy in humans living with neuropsychiatric and neurologic disease, including
veterans and active duty soldiers suffering from mental health issues.” (Underwood 2013)

RAM specifically focused on recovering memory for those individuals that have lost their memory following brain injury. The solicitation for the program stated:

“DARPA seeks new methods for analysis and decoding of neural signals in order to understand how neural stimulation could be applied to facilitate recovery of memory encoding following brain injury.” (Underwood 2013)

In 2015, $80 million was dedicated solely to BRAIN initiative-specified research by DARPA. The number of programs that were funded increased, as new programs built on knowledge gained through previously funded programs. As published by the White House BRAIN initiative propositions:

“DARPA’s investments aim to leverage brain-function research to alleviate the burden of illness and injury and provide novel, neurotechnology-based capabilities for military personnel and civilians alike.” (“Obama Administration Proposes Doubling Support for the BRAIN Initiative.” 2015)

DARPA’s BRAIN initiative funded programs will:

“Create interfaces for handling and analyzing large datasets of neural data, allowing investigators to rapidly and transparently solve complex problems of computation, generate new models, and model the brain in multiple dimensions and spatiotemporal scales.” (“Obama Administration Proposes Doubling Support for the BRAIN Initiative.” 2015)

In 2016, $95 million was dedicated solely to BRAIN initiative-specified research by DARPA.

As published by the White House BRAIN initiative propositions:

“DARPA’s investments aim to leverage brain function research to alleviate the burden of illness and injury and provide novel, neurotechnology-based capabilities for military personnel and civilians alike.” (“Obama Administration Proposes Over $300 Million in Funding for the BRAIN Initiative.” 2016).

The portfolio of DARPA-funded BRAIN initiative-specific programs increased a lot more as their knowledge about the brain increased. Programs at DARPA continue to accelerate and take the BRAIN initiative goals to another level:
“Parallel investments in physiological research and technology development will yield more complete understanding of the neural circuits involved in regulating health.” (“Obama Administration Proposes Over $300 Million in Funding for the BRAIN Initiative.” 2016).

Two programs from DARPA focusing on translational neuroscience:

1. Hand Proprioception and Touch Interfaces (HAPTIX)- The purpose of the program is to award researchers with funding in the areas that will enable/create a prosthetic hand system that moves and feels like a natural human hand. The goal is to make the users of the prosthetic hand get the same type of “natural” feeling someone gets without a prosthetic arm (“Hand Proprioception and Touch Interfaces.” 2016).

2. Electrical Prescriptions (ElectRx)– the purpose of the program is to award researchers with funding in the areas which will enable/create ways to modulate the peripheral nervous system to fight diseases. The program envisions to treat conditions such as post-traumatic stress disorder, inflammatory diseases, depression, and different parts of the body dealing with chronic pain (“Electrical Prescriptions.” 2016).

DARPA, as an agency within the Department of Defense (DoD), has to follow and abide by not only the federal ethical and legal policies and guidelines but also has to abide by the DoD ethical and legal guidelines. For example, when DARPA funds an extramural performer to conduct a BRAIN initiative funded study, the research has to be reviewed by both the local and the DoD headquarters-level institutional review boards, prior to any research. Per DARPA’s funding guidelines, the ethical guidelines and policies that the research must meet and abide by are 45 Code of Federal Regulations 46 “Protection of Human Subjects”, Department of Defense Instructions 3216.02 “Protection of Human Subjects”, and Department of Defense 32 Code of Federal Regulations 219 “Protection of Human Subjects in Research”, in addition to DARPA’s internal policies governing their funded research. In addition, all DoD funded research must

NIH

The roots of NIH can be traced back to 1887, starting from a one-room lab within the Marine Hospital Service (which provided medical care to seamen), and was called the Hygienic Laboratory. In 1891, this lab moved to Washington, D.C., and in 1904, the lab changed into a center for research within the Federal government (Office of NIH History. 2015). In 1930, the Ransdell Act was enacted and the name National Institute of Health was given to the establishment. During World War II, the investigators focused entirely on WWII problems, such as testing for lead or TNT in urine samples of workers. From 1946 to 1949, several different institutes were formed under NIH (Table 2):

Table 2. List of the original seven institutes created under the NIH agency.

<table>
<thead>
<tr>
<th>Institute</th>
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<tr>
<td>National Cancer Institute</td>
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<tr>
<td>Division of Research Grants</td>
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<tr>
<td>National Heart Institute</td>
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<tr>
<td>National Microbiological Institute</td>
</tr>
<tr>
<td>Experimental Biology Medicine Institute</td>
</tr>
<tr>
<td>National Institute of Dental Research</td>
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<tr>
<td>National Institute of Mental Health</td>
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By 1960, these original seven changed to 10 institutes; by 1970, it was 15 institutes and by 1998, it had formed 27 institutes and centers, which stands to be the same number today. Each institute specializes in its own area, but caters to the overall mission of NIH to reduce illness and disease and increase healthy living (Office of NIH History. 2015).
Table 3. A list of the current 27 institutes currently under the NIH agency.

<table>
<thead>
<tr>
<th>National Cancer Institute</th>
<th>National Institute of Biomedical Imagining and Bioengineering</th>
<th>National Institute of Mental Health</th>
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<tbody>
<tr>
<td>National Eye Institute</td>
<td>National Institute of Child Health and Human Development</td>
<td>National Institute on Minority Health and Health Disparities</td>
</tr>
<tr>
<td>National Heart, Lung, and Blood Institute</td>
<td>National Institute on Deafness and Other Communication Disorders</td>
<td>National Institute of Neurological Disorders and Stroke</td>
</tr>
<tr>
<td>National Human Genome Research Institute</td>
<td>National Institute of Dental and Craniofacial Research</td>
<td>National Institute of Nursing Research</td>
</tr>
<tr>
<td>National Institute on Aging</td>
<td>National Institute of Diabetes and Digestive and Kidney Disease</td>
<td>National Library of Medicine</td>
</tr>
<tr>
<td>National Institute on Alcohol Abuse and Alcoholism</td>
<td>National Institute on Drug Abuse</td>
<td>Center for Information Technology</td>
</tr>
<tr>
<td>National Institute of Allergy and Infectious Diseases</td>
<td>National Institute of Environmental Health Sciences</td>
<td>Center for Scientific Review</td>
</tr>
<tr>
<td>National Institute of Arthritis and Musculoskeletal and Skin Diseases</td>
<td>National Institute of General Medical Sciences</td>
<td>Fogarty International Center</td>
</tr>
<tr>
<td>National Center for Advancing Translational Science</td>
<td>National Center for Complementary and Integrative Health</td>
<td>NIH Clinical Center</td>
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</table>

NIH is the nation’s leading medical research agency, with over 2000 employees. It holds true to its mission of advancing fundamental knowledge about reducing disease and increasing healthy lives. NIH-funded research is not conducted under the fast-paced, short-term framework. Since program managers do not have a limited number of years or terms to serve, they tend to give their researchers projects and timelines that are much longer. This results in research studies that last over a greater span of time to produce quality results and treatments for the general public. Therefore, when the President’s initiative called on NIH to advance health human lives, through translational neuroscience research and technology, NIH was first in line to take the goal one step further. In 2014, $40 million was dedicated to just BRAIN initiative-specified research. As published in NIH’s FY 2014 congressional justification for budget:
“In FY 2014, NIH will begin its support of the Brain Research through Application of Innovative Neurotechnologies (BRAIN) Initiative, in order to develop a deeper understanding of brain function through the creation of new tools capable of examining the activity of the millions of nerve cells, networks, and pathways in the brain in real time.” (Department of Health and Human Services, National Institute of Health-FY2014 Budget.” 2014)

In 2015, $100 million was dedicated to just BRAIN initiative-specified research. As published in NIH’s FY 2015 congressional justification for budget:

“The BRAIN Initiative will build on the rapidly growing scientific foundation of neuroscience, genetics, physics, engineering, informatics, nanoscience, chemistry, mathematics, and technological advances of the past few decades to catalyze an interdisciplinary effort of unprecedented scope.” (“Obama Administration Proposes Doubling Support for the BRAIN Initiative.” 2015).

NIH programs are focusing on:

“Building a new arsenal of tools and technologies for studying the brain. This state-of-the-art “toolbox” will include a systematic inventory of all the different types of cells in the brain, targeted genetic and non-genetic approaches for accessing specific cells and circuits, new and better capabilities for recording from rapidly firing collections of neurons, and interdisciplinary approaches to understanding how brain circuits produce unique human functions.” (“Obama Administration Proposes Doubling Support for the BRAIN Initiative.” 2015).

In 2016, $135 million was dedicated to just BRAIN initiative specified research. As published in NIH’s FY 2015 congressional justification for budget:

“Through this initiative, NIH and its partners are driving the development and use of innovative technologies to produce a clearer, dynamic picture of the brain that can show, for the first time, how individual cells and complex neural circuits interact in both time and space.” (“Obama Administration Proposes Over $300 Million in Funding for the BRAIN Initiative.” 2016).

Programs at NIH continue to develop new treatments and tools to assist with the BRAIN initiative goals:

“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.” (“Obama Administration Proposes Over $300 Million in Funding for the BRAIN Initiative.” 2016).

Two programs from NIH focusing on translational neuroscience:

1. Next Generation Human Imagining- The purpose of this program is to award researchers with funding that focuses on three areas: (1) Precise Interventional Tools: link brain activity to behavior through development of next generation tools that first will be tested in animal and then humans focusing on optogenetics, chemogenetics, and biochemical and electromagnetic modulation. (2) Advance Human Neuroscience: understand and to treat the human brain through development of innovative technologies. (3) Techniques to Monitor Neural Activity: monitor the human brain through establishment of methods to conduct large scale monitoring of neural activity (“The BRAIN Initiative: Funded Awards.” 2016).

2. Next Generation Human Invasive Devices- The purpose of this program is to award researchers with funding that focuses on three areas: (1) Precise Interventional Tools: link brain activity to behavior through development of next generation tools that first will be tested in animal and then humans focusing on optogenetics, chemogenetics, and biochemical and electromagnetic modulation. (2) Advance Human Neuroscience: understand and to treat the human brain through development of innovative technologies. (3) Techniques to Monitor Neural Activity: monitor the human brain through establishment of methods to conduct large scale monitoring of neural activity (“The BRAIN Initiative: Funded Awards.” 2016).

NIH, as an agency within the Department of Health and Human Services (DHHS), has to follow and abide by the federal ethical and legal policies and guidelines. For example, when NIH funds an extramural performer to conduct a BRAIN initiative-funded study, the research has to be reviewed by both the local and the NIH headquarters-level institutional review boards, prior to any research. Per NIH’s funding guidelines, the ethical guidelines and policies that the
research must meet and abide by are 45 Code of Federal Regulations 46 “Protection of Human Subjects”, in addition to NIH’s internal policies governing their funded research. In addition, the researchers must abide by the NIH’s internal legal clauses and guidelines.

In summary, both NIH and DARPA have Directors that are Presidential appointees. Most of the directors are changed or replaced when new administration takes office, as every Presidential administration has their own mission and vision for the agencies. However, DARPA and NIH as agencies have different missions. DARPA’s mission is to utilize strategies that enable a fast, efficient, work environment to produce high-quality products to aid the warfighter and civilians. However, NIH’s mission is to enhance health and reduce illness; focusing their work on the health related-translational neuroscience facilitates the accomplishment of their mandated goals. DARPA’s focus is more technologically based, while NIH’s mission is geared towards health advances. Table 4, generated from OMB, NIH and DARPA budgetary documents provides an overview of BRAIN initiative funding allocations per agency for FY 2014, 2015, and 2016 (Per Research and Development budget allocations from OMB in million dollars):

<table>
<thead>
<tr>
<th>Agency</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>DARPA</td>
<td>38</td>
<td>80</td>
<td>95</td>
</tr>
<tr>
<td>NIH</td>
<td>40</td>
<td>100</td>
<td>135</td>
</tr>
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Thus, it should be interesting to explore how DARPA and NIH, two agencies that have Presidential appointed Directors, but are so vastly different in their mission, vision, and structure along with Federal alignment (which changes the policies and guidelines they have to adhere to for ethical and legal issues; DARPA/DoD and NIH/DHHS), follow the same initiative.
Now, that we understand what these agencies do, and what the programs are, let us shift our focus onto the ethical, legal, and societal implications of these programs and what it means for the future and acceptance of neuroscience and technology research.

The Literature on the Ethical Dilemmas of Neuro S&T Research and Use

Ethical issues surrounding the neuro S&T are diverse, from lack in regulatory guidance to ethical implications of new drugs and technologies, data security, and autonomy.

a. Lack of Ethical Regulations

All federally funded agencies must abide by the regulation 45CFR46 (“Code of Federal regulations.” 2009), also known as “the common rule” when conducting research involving human subjects. As stated in 45CFR46.102, the common rule directs the reviewing authorities to evaluate risk based on the knowledge that is being gained when reviewing human subjects research. At present, all federally funded brain research involving humans is regulated by the common rule. When humans are part of a federally funded study in any way, the research being conducted has to be held up by the ethical standards set forth in the common rule. The common rule was set up by the principles of the Belmont report. Drafted in 1979, by members of the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, the “Belmont report” states three basic principles when drafting, conducting or reviewing human subjects research. The three basic ethical principles are respect for person, beneficence, and justice. The Belmont report, does not provide specific procedures on how to follow these principles, but more so provides an ethical framework for individuals to follow.

Developed based on the principles of the Belmont report, the common rule has three categories of protected classes with additional guidelines that need to be followed: prisoners, women and children. For individuals that are mentally incapacitated or have a mental
disorder/disability, there is no special category, per 45 CFR 46. The research that is being funded for neuro S&T research will need to be tested on patients that have neurological conditions. These subjects, that have neurological disorders, fall into the mental disorder/disabled or the vulnerable population category (Ruof. 2004). Therefore, either a category or additional guidance needs to be provided by 45 CFR 46 for subjects in this category (Chhatbar and Saha 2012, 99).

Per National Bioethics Advisory Commission, a major ethical concern for neuro S&T research is the lack of understanding of the current state of mind of a mentally disabled individual (National Bioethics Advisory Commission. 2001). For example, individuals with schizophrenia or dementia have windows of clarity (with or without medication). When is their consent for a research study valid? Which “subject” is consenting to the research? (Blank 2013, 66) Second, individuals who suffer from diseases like Alzheimer have full awareness and mental capacity but eventually will lose that mental capacity. What happens to their consent in the future of that trial? Third, individuals with limited mental capacity may still understand things to some extent but are not legally required to have a representative. How should a researcher handle their participation, especially when the researcher knows that they are not fully comprehending the risks involved? Finally, for subjects that have no mental decision-making capability, the common rule does provide guidance (Kulynych. 2002). For those suffering from a mental disability, the common rule states that a legally authorized representative (LAR) must be present to ensure that voluntary informed consent occurs prior to participation of the subject in the research study. But no law or ethical guideline provides guidance on who is constituted as a LAR in a research setting and when and to what extent their role applies (“Informed Consent Guidance.” 2012). Figure 2, generated from the questions risen by authors discussing the
decision-making capacity of subjects with mental disorders, provides a visual for these four types of subjects with decision-making capacity and how their capacity changes over time due to their disorder.

Figure 2. Decision-making capacity of subjects with mental disorders.

Open interpretation of the Belmont principles and minimal guidance available through the common rule and no additional ethical regulations mandated by the federal government, brain research is currently being reviewed by institutional review boards (IRBs) with guidelines that they see fit, resulting in ethical gap between applying the principles or simply checking boxes that regulations are being followed. A lot of times while developing, conducting or reviewing policies, it’s not that individuals don’t want to apply the principles, but they simply don’t know what the ethical problem is, or lack the knowledge to understand the ethical problem. Issues such as these stem from lack of understanding or knowledge of the research project itself and its implications. Therefore, ensuring those that are developing, conducting, or reviewing research are adequately trained is imperative to human subjects research. Compliance is important but should be more than just following the regulations and checking off boxes on checklists. There is a fundamental lag in understanding of the ethical principles that originated
these policies. The individuals involved with the design, the conduct and the review of research should be focusing on the underlying ethical principles of these policies and not just the policy itself. “Research involving human subjects should be a partnership between the subjects who volunteer for the research, the public who hope to benefit from future drugs, devices, and biological products, investigators who design and conduct research, sponsors (institutions and companies that design, conduct, and sponsor or fund research), and IRBs who review research.” (Perlman 2006, 14).

Issues of ensuring adequate measures are taken by researchers to obtain consent were raised by the Presidential Commission for the Study of Bioethical Issues in Gray Matters, volume 1 and 2 (Gray Matter. 2015). The issues of participants’ autonomy, freedom, fairness, safety and consent is a major ethical hurdle being faced by researchers and subjects (Bostrom and Sandberg. 2009). While research is conducted to gain generalizable knowledge, ensuring minimization of risk should be a major part of each protocol’s research design, especially when dealing with a population which has a limited decision-making capacity. Noninvasive neuro S&T, as being conducted through one program and being reviewed in this study from DARPA and one program at NIH, tend to be safe for use. However, the imaging seen through noninvasive technologies to date, tend to lack the temporal and spatial resolution that invasive technologies provide, but invasive imagining technologies come with their own set of complications and risks. The guidelines currently being provided by IRBs, FDA, and DHHS apply minimum reviewing standards. In light of development of these new technologies, these guidelines must be revised to keep up with the changing technology (Chhatbar and Saha 2012, 99).
b. Enhancement

Another ethical issue that arises from literature review of neuro S&T is the enhancement of “normal” function. In the previous section, we dealt with issues surrounding individuals that needed neuro S&T treatments due to a medical condition, but what about “normal” individuals that want enhancement through these technologies? How do we as deal with the ethics of someone wanting to enhance their mood, appetite, or cognitive function? Farah (2002) goes into detail on some of the issues surrounding neuro S&T and the role of treatments that “enhance” human functions. Two potential ethical issues arise from “enhancement.” First, if an individual is taking drugs to enhance their memory compared to someone who either cannot or will not, the user taking the enhanced drugs has an unfair advantage over the other.

Second, the human life experience is full of different moods. If an individual takes drugs to stay in one mood all the time, are they truly experiencing life in its truest form, that is, a life full of the various human emotions of happy, sad, confusion, and excitement? As Bostrom and Sandberg (2009) term it, “the good life” experience will be missed. These two issues lead us to the overall societal ethical problem of potentially changing the level of “normalcy” (Farah 2002). If most individuals in society choose to enhance, will that shift what we consider normal to another caliber? In addition, what about those individuals that choose not to enhance? Now they may be at a disadvantage that did not exist before, if it was not for neuro S&T research.

The use of prosthetics or other neuro S&T devices, as being looked at specifically through one program at DARPA and one at NIH, can either be used to restore function of an impaired part of an individual or to enhance function of a part of the body, which an individual did not possess before use of the technology. This issue of enhancement through the use of neuro S&T brings us to the issue of fair distribution or use, where individuals in society that can afford
the technology can, in essence, have an unfair advantage over those that cannot afford the technology for cosmetic use (Chhatbar and Saha 2012, 100).

c. Data Security and Privacy

Another issue raised by these technologies is about maintaining data security and privacy. Especially in using imaging devices and storage of information virtually, ensuring proper security of this data, which contains personally identifiable information, is a real issue. Researchers have been working towards collaborations and data sharing, but ensuring all this happens safely and securely should be their primary responsibility (Keiper 2012, 143). The potential threat of data breaches or “hacks” are always looming and can make the public very apprehensive about having their medical data shared.

d. Autonomy

Another issue that neuro S&T device use raises is the issue of autonomy. Through the therapeutic use of transcranial or deep brain stimulation, can researchers end up altering a person or their identity? But what we have to understand is when participating in these research projects, does the alteration of the personality affect the autonomy or the individual’s sense of well-being (Fabrice and Giordano 2012, 108). In these cases, benefit vs. harm has to be assessed for the individual participating in the study. If the individual is receiving benefit, then is the side effect of identity change or loss justifiable? If the quality of life for the individual is increasing due to the therapeutic intervention, then is the loss of autonomy justified (Fabrice and Giordano 2012, 120). These are questions that only the specific individual or their legal representative can answer, as the rule of thumb principle does not apply in these scenarios.
The Literature on the Legal Dilemmas of Neuro S&T Research and Use

The use of neuro S&T research in the court room, whether in civil or criminal cases, has increased significantly in the last couple of years. In recent years, neurolaw has become a field of study on its own. Prediction of whether an individual’s actions are due to an injury they sustained in their brain is a very slippery slope and also takes us into the medical liability arena (Kulynych 2002). With emergence of biomedical technology and its use in the court room, we have a rising number of experts that are willing to testify in court and provide their expert testimony in cases to understand the behaviors of individuals based on these technologies. While these new technologies can be extremely beneficial in their use, they have their limitations (Rich. 2005). In order to better understand which federal rules of evidence currently apply and how they are affected by testimonies of neuroscientists in court, let us look at them closely:

- Frye Standard—was one of the first standards to be passed. It was and is still used by some states as the baseline, whether scientific evidence should be admitted as a reliable source to make decisions in court (“Frye Standard.” 1923). The scientific technology being used should be tried and tested and be held acceptable to be allowed for use in a case.

- Daubert Standard—is generally used as the baseline, whether a scientific expert being used for a witness’s opinion should be admitted in court. The judge must use his/her own judgement to allow for the expert witness’s testimony to be allowed in court. The judge must ensure that the testimony is based on scientific facts and data (“Daubert Standard.” 1993).

- Federal Rules of Evidence (FRE) 702—Testimony by Expert Witnesses: which has been revised to include both the Frye and the Daubert standards, are based on the
substance, quality, and boundaries of a witness who is an expert in his/her field and can testify through their opinion on the subject in court. The witness can testify if their knowledge will help the court understand the facts of the case; their opinion in the testimony is based on facts; their testimony is based on dependable principles; and the witness has applied all the facts and principles of his/her discipline to the case being presented in court (“Rule 702, Testimony by Expert Witness.” 1975).

The use of fMRI, in the court room has been seen many times. While experts can use the fMRI to deduce how the image can relate to the event in the question, that is solely based on that individual expert’s opinion. Technologies currently being developed by DARPA and NIH, will be able to increase our understanding of human behavior, action, and maybe even intent. Focusing on the two programs selected from both agencies, let us closely examine the impact they can have on the legal justice system.

a. Justice and Responsibility

Based on the democratic theory, individuals make choices based on their own free will and any force beyond their control is an external factor that must be considered. For neuro S&T, does that mean the individual is no longer responsible, as they do not have complete control of “self” (Blank 2013, 130)? Common sense tells us that if an individual commits a crime, they are responsible for it. However, if an external agent enters the scenario such as using a particular drug or having a device inserted in your brain, is the individual still responsible or does the undesirable outcome become the responsibility of the treatment/device? This type of scenario makes the justice system question the laws as currently written. Some neuro S&T research technologies will make it impossible to separate the individual from the device, thus making the notion of “responsibility” very hard to apply in legal proceedings (Blank 2013, 133).
Bloch and McMunigal (2005) suggest that there are four justifications for punishment:

1. **Retribution** - where criminals are punished for their crime. In these cases, punishment should be equivalent to the intensity of the crime committed or damage caused.

2. **Deterrence** - where punishment should be designed to prevent future crime from happening. Future criminals should look at an individual’s sentence and it should deter them from committing a crime.

3. **Incapacitation**: where individuals that commit crime should be taken off the street. This way, future crime will be prevented, as the individuals committing them will be in prison.

4. **Rehabilitation**: where punishment is provided to criminals to rehabilitate them. This will ensure that even upon release they will not commit any future crimes, as they will be rehabilitated.

Let us review some legal cases where neuro S&T was involved and the impact it had on the outcome of the trials:

1. **Roper vs. Simmons (2005)**: A seventeen-year-old man was on trial for murdering a woman. At the legal proceedings, neuroimaging evidence was submitted to show that adolescent brains lack the decision-making capacity that adults brain possess, they tend to be more prone to take risks, and are more aggressive; therefore this man should not be held responsible and punished as an adult. The individual’s neuroimages were submitted as part of testimony. While it is unclear if the neuroimages or the argument swayed the punishment, the individual was not sentenced to death after the evidence was presented (Blank 2013, 137).

2. **Graham vs. Florida (2010)**: The court stated that for an individual under the age of eighteen, a sentence of life without parole is a violation of the Constitution’s
prohibition of cruel and unusual punishment, except in the case of a homicide. Therefore, in these cases, the court stated that neuroimages of the adolescents must be looked at to see if the white matter structure of the individual is adult-like or not. The court will use the neuroimages to guide its sentencing in such cases (Blank 2013, 137).

3. Daubert vs. Merrell Dow Pharmaceuticals (1993): The judges have the responsibility to assess the impact of the scientific/medical evidence being introduced in the court proceedings. If the judge discerns that the evidence will persuade the jury in the wrong way, then the judge can dismiss the evidence from being used in the trial. For neuroimages to be used in a successful manner in the court, they must be able to link the neuroimages with how the person was thinking or acting at the moment the crime was committed (Blank 2013, 143).

4. Kansas vs. Hendricks (1997): in certain cases of mental illnesses, individuals suffering from them are excused from punishment, if, at the time of committing the crime, they are found to be suffering from that condition. However, in the case of Kansas vs. Hendricks, the court allowed for increased “punishment” for a sexually violent predator that committed a crime while suffering from the excusable mental illness (Blank 2013, 144).

5. Panetti vs. Quarterman (2007): in this case, the issue was whether an individual that has a mental illness/disability can be executed on death row. The court ruled that, in cases such as these, the defendant has a constitutional right to show why the state’s reason for his execution was obstructed due to their lack of understanding of his mental illness. Different scholars feel very differently about this ruling. While
scholars like Snead believe that rulings based on neuroimages are going to let criminals get away from deserved punishment, others like Eagleman and Sapolsky believe differently. They think these new techniques will provide a linkage between trauma and behavior and have the potential to change the criminal justice system (Blank 2013, 146).

In the case of neurolaw and utilization of these technologies, it is imperative that the court does not ask the experts to make leaps of faith or to make inferences based on their expertise. The experts should simply be involved to use the techniques and present the data. Making decision based on the imaging is not something the expert should be involved in. The legal implications being faced by these technologies if not used properly can lead to injustice and result in unfair trials (Farah 2002). As we can see through review of these cases, legal proceedings are not clear cut. Sometimes courts rely on these neuroscience and technologies, while other times they have to deliberate based on other evidence or the situation at hand (as in the case of Kansas vs. Hendricks).

**The Literature on the Nature and Extent of Societal Views in Neuro S&T Research and Technology**

Societal views surrounding neuro S&T are diverse and seem to be evolving, as the perception and education of society changes. The research and policy literature identifies several significant concerns associated with the development of technologies involving the brain and their impact on the society. The implications of distribution of goods, justice, and fairness are among many others that rise as a problem. Knowing what the two programs from DARPA and NIH are producing, let us examine closely what impact they can have on society.
a. Unequal Distribution of Goods

An individual with access to the technology or treatment compared to another individual that does not have access will have an unfair advantage. This will only add to the existing inequalities already being faced by an individual with no accessibility, leading to problems of justice and fairness (Bostorm and Roache 2009, 143). Currently, these technologies are in their infancy stage of development. We do not know the extent of coverage that will be provided by insurance and/or Medicaid on the use of these new technologies/therapies (Farah 2002). These will be additional hurdles that policy makers will need to overcome in order for their use by the society and to ensure equal distribution of treatment.

To date, cost of neuro S&T is high, and while researchers are working to ensure the cost comes down, it still raises issues of distributive justice. The resources of funding and commercialization are finite, while the use and demands of these technologies have the potential to be infinite (Blank 2013, 72). This is especially unjust in the U.S., where we do not have a single payer system. Out-of-pocket costs for new medical treatments/technologies tend to be astronomical and an average person in the U.S. cannot afford them. In addition, health insurance companies tend to either pay part of a new treatment/technology or refuse to cover it based on their own rules and regulations. This raises a very interesting argument should we be focusing on developing these technologies when we do not know the extent to which they will be accessible to the general public? Or should we focus our funding first on making sure everything is accessible to everyone and then move onto medical advances? This argument takes us into the age-old argument of equality and equal access for all (Blank 2013, 73). While there is not a definitive answer for it, policy makers should keep this in mind when funding and figure out the costs of these technologies.
b. Limited Understanding of the Brain

Another problem being faced by the society is limited understanding of the brain. Due to the novelty of the research being conducted on the brain and the limited literature available to public in layman terms, the research is not understood clearly by the general public. The main source of the general public’s education is obtained through the media, which in some cases report to make headlines and not the true facts. Racine, DuRousseau, and Illes (2008, 175-190) explained how a simple experiment that was funded by DARPA ended up being portrayed completely different from what its original intention was. The paper, titled “Rat Navigation Guided by Remote Control” (Racine et al. 2008, 176), was published in Nature in 2002. Within two weeks of the paper’s publishing date, approximately 43 articles were written and published about the same experiment. Quickly the rats were named “roborats” by the media and the experiment which showed microstimulation of the rats’ brains was described as “Hi-tech rats soon on bomb squad” (Racine et al. 2008, 176). The public was outraged at what scientists were doing to rats in their labs, from ethicists to animal rights groups, activists, religious leaders; everyone had something to say. Only those that knew the technical terminology and read the publication knew exactly what had taken place.

c. Age of the Internet (reliable/unreliable information)

The lack of understanding of the science behind the brain adds to the public’s apprehension towards neuro S&T research. Zey (2004, 85), speaks of the public’s hesitation due to their lack of understanding of science. These groundbreaking discoveries being made have the potential to change our future and treat diseases that we have no cure for today. These technologies can only make a difference if the public truly sees them for the benefits they have and the difference they can make for the future generations (Roberts 2002). A problem which goes hand-in-hand with the lack of education is education through unreliable sources. In the age
of the internet, every individual that has access to the internet has the ability to diagnose/misdiagnose and treat/mistreat their own condition. Now, with issues of neuro S&T, where information is published through all sources, from reliable to unreliable sources, the general public or the consumer of these technologies have the option to educate themselves on all issues as they see fit. They can either go to a researcher or their clinician to confirm the information they have discovered or just go off their own research and make up their mind. This type of data gathering has both pros and cons. If someone is researching and making up misconceptions in their own brain about what this technology can do, these notions can be about how well the technology can act or how bad. Either way, without proper advice and consultation, misinformation can hinder the true nature of the research technology being researched (Chhatbar and Saha 2012, 99).

d. Stigma of Mental Illness

An issue which mental health patients have dealt with from the beginning of time is of stigmatization. Our society tends to stigmatize individuals that seek medical mental health treatment. With limited understanding of the brain and treatments, some individuals tend to stay away from a doctor even when they need treatment the most, because they do not want to be labeled crazy (Blank 2013, 65). This issue brings together all other societal issues under one label, as the proper education of our society is imperative to the success and usefulness of these technologies. Research shows that these technologies have the potential to achieve greatness by bringing cures to diseases, which are increasing at an exponential rate.

In the U.S., adults with mental health problems constitute 43.8 million of our current population, per statistics from the NIMH (Substance Abuse and Mental Health Services Administration. 2013). Therefore, they were looking to find solutions for the large population,
which is affected by this very real problem. Use of these technologies and patients seeking medical intervention at the right time will help researchers and clinicians provide care and conduct research in real time to figure out a successful path forward. Individuals are potentially afraid of being discriminated against, by society or more specifically in the work force, or for medical benefits (Blank 2013, 70). As more of these technologies and treatments become available, we are sure to learn of new mental disorders, which we were not aware of before. With individuals afraid of being stigmatized or discriminated against, figuring out a smooth path forward for them should be a part of the neuro S&T policy that must be addressed.

Summary of Literature Review

In summary, the literature review generated after review of publicly available documents, scholarly and academic research articles, books, federal and legal documentation on neuro S&T research’s ethical, legal, and societal views gives us a lot of issues to consider. The interview questions for agency leaders and scientific community will be generated based on these issues for this study, in order to figure out how they are currently addressing these concerns and limitations through policy and study design. Finding out their strategies and plans on how they propose to or are removing these limitations will help in addressing public concerns of utilization and accessibility. Thus, in the next chapter, we will generate the research questions for this study based on the following issues:

- Ethical - lack of regulations, enhancement, data security and privacy, autonomy, freedom, fairness, and safety for the public, which generates concerns for informed consent, equity among all groups, and minimization of risk for all.
- Legal - justice and fairness. As these issues give rise to problems of using brain technologies to make assumptions about defendant behavior. Utilization of neuro
S&T should not inhibit the right to obtain a fair trial that is free of judgement by all.

- Social- justice in the distribution of the existing and potential goods and services generated by neuro S&T research, limited understanding of the brain, age of the internet (reliable/unreliable information), and stigma of mental illness. Leading us to our overall concerns with access and quality of health care, fair distribution of treatment and new technologies beyond giving health care advantage to some over others.

The literature review will assist in establishing the methodology and design of this study in order to address the ethical, legal questions and societal views on neuro S&T research by interviewing agency leaders and the scientific community, reviewing data from public surveys, and analyzing research and development funding allocations (specific to the BRAIN initiative), in order to better understand the influence of Presidential initiatives on agencies, the resulting product, and the effect it has on the general public.
CHAPTER 3

RESEARCH METHODOLOGY

The purpose of this chapter is to indicate the methodological logic and design to test the hypotheses of this study and to address the central research question of this study. The central research question to be addressed in this study is how agencies that follow the Presidential BRAIN initiative address ethical, legal and societal views on neuro S&T research. Specifically, several subsidiary questions will be addressed as a result of the findings:

- What types of ethical questions does the science involving translational neuroscience research raise for the public (and who raises these questions)?
- What types of legal ramifications do these ethical questions raise and how does public policy address these ramifications?

The programs at DARPA and NIH will give insight into the societal and ethical impact of neuro S&T research. Data were collected using mixed-method methodology techniques to include interviews, survey databases, and archival record review. This way, more than one method was used to collect data. If the findings from all of the methods draw similar conclusions, then validity and reliability in the findings will be established.

The hypotheses of this study, generated largely from the scientific, policy, legal, and opinion literature are:

- H₁: If an agency’s leadership is a Presidential appointee, and a Presidential Initiative falls within their mission, then the agency is pressured to focus their work to align with the initiative.
• $H_2$: If societal needs outweigh the ethical and legal risks associated with a particular neuroscience and technology research, then the research will be funded by an agency, contingent upon a mitigation strategy.

Methodological triangulation techniques will be applied using a mixed-method methodology to include interviews, survey databases, and archival record review. This way, not just one method will be used to collect data. If the findings from all of the methods draw similar conclusions, then validity and reliability in the findings will be established. In addition, mixed methods will be utilized to understand similarities and contradictions between quantitative and qualitative findings. This will ensure that the findings are grounded in the study participant’s attitudes, values, and beliefs.

**Research Design**

The study was divided into three parts, (I) agency and researcher interview, (II) review of public survey data on neuro S&T, and (III) archival analysis of research and development funding specific to the BRAIN initiative for FY 2014, 2015, and 2016.

Part I- While there are several methodological schools of phenomenological research, the approach used in this study is developed initially from Heidegger’s philosophy on phenomenology. His methodological guidance for qualitative researchers assists in understanding the lived experience of study participants (Horrigan-Kelly, et al. 2016).

Specifically, how experiences/actions arise from brain activity in an individual. Therefore, in this study, it was assumed that the participants are: (1) not radically free but situated "within meaningful activities, relationships, commitments, and involvements that set up both possibilities and constraints for living;" (2) first engaged at a basic unreflective level and only later engaged at a more theoretical or reflective level; and (3) "those things that matter to a person, set up how
a person enters a situation, what is seen and unseen, and how the person acts” (Benner et al. 2009, 306-334). This specific study thus begins with the following assumptions based on epistemology as outlined by Riccucci (2010). First, it is assumed that participants in this study share with others and society a negotiated view of what it means to be “good.” Second, it is assumed that dilemmas of ethics are ubiquitous in their frequency and their scope, for both researchers and agency personnel in their daily interactions. Therefore, the approach in this study involved being open to the commonness of everyday ethical issues, as experienced by agency personnel and researchers in their day-to-day.

To conduct this study, I chose two programs from DARPA and NIH. Interviews were then conducted with agency personnel who were administrators, policy makers, and/or science/technology specialists at DARPA and NIH. As proposed, interviews were conducted with agency personnel to understand strategies for implementation of initiatives and allocation of funding in order to establish ethical and legal dimensions in public policies associated with neuro S&T research. Potentially 3-5 personnel per agency were interviewed, with at least one person in the capacity of administrator, one policy maker, and one S&T specialist.

Along with institutional participants at DARPA and NIH, interviews were conducted with scientists and researchers conducting the neuro S&T research. These interviews were to assist in establishing ethical and legal dimensions in public policies associated with neuro S&T research. Potentially 5-10 scientists and researchers were to be interviewed per agency, selected based on the programs that they are working on. As described by Luton (2010), a quantitative methodology utilizing a survey research instrument was followed in this study. The instrument was validated through review by the dissertation committee and mentors at the selected agencies. A draft survey instrument was developed based upon a review of the literature and distributed to
the selected panel for review. The review and rewrite process involved four iterations of the
instrument before the panel affirmed the content and format of the survey was valid. In addition,
the questionnaire that was used to interview the personnel was approved by the University of

In early July 2016, the revised instrument was distributed among agency personnel and
research scientists at DARPA and NIH. The survey instrument was distributed to agency
personnel and research scientists that were associated with the selected programs at DARPA and
NIH:

1. Next Generation Human Imaging

The purpose of this program is to award researchers with funding that focuses on three
areas: (1) Precise Interventional Tools: link brain activity to behavior through development of
next generation tools that first will be tested in animal and then humans focusing on
optogenetics, chemogenetics, and biochemical and electromagnetic modulation (“The BRAIN
Initiative: Funded Awards.” 2016). (2) Advance Human Neuroscience: understand and to treat
the human brain through development of innovative technologies. (3) Techniques to Monitor
Neural Activity: monitor the human brain through establishment of methods to conduct large
scale monitoring of neural activity. This can be facilitated through electrodes, optics,
nanoscience, and molecular genetics.

Researchers at Vanderbilt University, Massachusetts Institute of Technology, University
of Arizona, Yale University, University of Minnesota, and University of California are among
those that have been awarded funds under this program. Some of the currently funded projects
under this program are focusing on development of the following:
a. Development of a technique to determine where in the brain a signal initiates (as seen in an EEG). Development of this technology will assist in mapping and understanding the neural network of the brain. Currently, this study is being conducted in healthy adults, and once mapping of a healthy brain is conducted, we can compare those to see where abnormalities and problems lie in individuals with brain injuries/illnesses (“The BRAIN Initiative: Funded Awards.” 2016).

b. Development of a noninvasive technique, sonoelectric tomography (SET) to tag specific locations of the brain using sound waves. This would result in being able to construct a tomographic image of the neocortex, and deep brain structures as well, which can potentially assist in diagnosing neuropsychiatric disorders. Also, it can be very helpful mapping the functions of brain circuits in healthy individuals.

c. Development of noninvasive techniques to study molecular events in the brain at a whole brain level (“The BRAIN Initiative: Funded Awards.” 2016). These studies are currently being conducted in mammals and, if successful, will be used to study neurotransmitter signaling in human brains (in real time). This would be a revolutionizing approach that will assist in studying diseases of the brain and be able to see them in real time.

1. Next Generation Human Invasive Devices

The purpose of this program is to award researchers with funding that focuses on three areas: (1) Precise Interventional Tools: link brain activity to behavior through development of next generation tools that first will be tested in animal and then humans focusing on optogenetics, chemogenetics, and biochemical and electromagnetic modulation (“The BRAIN Initiative: Funded Awards.” 2016). (2) Advance Human Neuroscience: understand and to treat the human brain through development of innovative technologies. (3) Techniques to Monitor
Neural Activity: monitor the human brain through establishment of methods to conduct large scale monitoring of neural activity. This can be facilitated through electrodes, optics, nanoscience, and molecular genetics.

Researchers at Massachusetts General Hospital, Baylor School of Medicine, Emory University, Cleveland Clinic, Mayo Clinic, and Weill Medical College of Cornell University are among those that have been awarded funds under this program. Some of the current funded projects under this program are focusing on development of the following:

a. Development of a device that can assist epilepsy patients to predict onset of seizure and be able to deliver therapeutic stimulations to limit seizure activity in the brain ("The BRAIN Initiative: Funded Awards." 2016). If successful, this life-saving device will enable epilepsy patients to be able to control their seizures, which currently cannot be controlled through traditional medicine or therapy.

b. Development of BrainGate, which is an implant in the brain giving an individual control of an external device, such as a prosthetic arm or leg. The goal of the program is to be able to give the patient total and complete access of the external device without carrying around any external components to control the device ("The BRAIN Initiative: Funded Awards." 2016). Eventually, the researchers want the patients to be able to carry on their normal lives and be able to use the external device independently without regular medical supervision.

c. Development of a therapy device for cognitive impairment associated with Traumatic brain injury (TBI). Currently, TBI affects 1.4 million individuals annually, resulting in cognitive disabilities which we do not have effective treatments for ("The BRAIN Initiative: Funded Awards." 2016). Researchers are trying to gather data by working with individuals that are...
currently suffering from TBI to inform successful development of next generation therapy device to resolve issues of cognitive impairment.

The two programs chosen from DARPA were:

1. Hand Proprioception and Touch Interfaces (HAPTIX)
   
The purpose of the program is to award researchers with funding in the areas that will enable/create a prosthetic hand system that moves and feels like a natural human hand. The prosthetic arms currently used give the user a feeling of being “numb” and therefore are not as effective as they can be or should be. The completed HAPTIX system will be integrated with the Revolutionizing Prosthetic’s (RP) program. The RP program was the first to create a dexterous prosthetic limb. Together with the HAPTIX system and the dexterous prosthetic limb, it will create a full “natural” prosthetic arm that has sensory and motor capabilities and will be completely suitable for home use. Researchers at Cleveland Clinic, Case Western Reserve University, Draper Laboratory, University of Pittsburgh, University of Utah, and University of Florida are among those that have been awarded funds under this program. Some of the currently funded projects under this program are focusing on:
   
a. To understand pressure (physical quantity of an experience of touch); researchers are working to understand how to encode graded sensations of pressure in the nervous system by the use of electrical stimulation. Understanding how the nervous system encodes different features of touch is an enormous task, but researchers are optimistic that they will be able to accomplish this. In the HAPTIX system, when the pressure sensors on a prosthetic arm are engaged by the user, they send signals to a stimulator (outside the user’s body). The stimulator then sends signals to the electrodes wrapped around the major nerve bundle (which are wrapped around the stump); these are the same nerve bundles that controlled the user’s arm prior to being amputated.
This stimulation is then carried to the brain and, in return, the brain interprets them to different levels of intensity (depending on the level or intensity of pressure applied). Researchers are currently testing these different levels of intensities in subjects, to see how little of an intensity the brain can detect.

Figure 3. An overview of the Hand Proprioception and Touch Interfaces system.

b. Another team of researchers is working to use commercially available technologies, such as lead technologies used in implantable medical devices and intramuscular electrodes to use as
part of the HAPTIX system (“Hand Proprioception and Touch Interfaces.” 2016). Researchers are working with the FDA, to come up with standards and guidelines for these new lines of technologies to ensure the technologies released to the general public are safe and reliable.

c. Currently, more than 80% of amputees experience “phantom limb pain”, which is the body’s way of making you feel pain from a body part that no longer exists. In the program, research teams are being comprised of psychologists, scientists, clinicians, and engineers to ensure that the developed system helps the end user not feel any disconnect from the prosthetic limb (“Hand Proprioception and Touch Interfaces.” 2016). The end goal is to have an end product that the user can use every day, comfortably, in every aspect of their lives.

2. Electrical Prescriptions (ElectRx)

The purpose of the program is to award researchers with funding in the areas which will enable/create ways to modulate the peripheral nervous system to fight diseases. The peripheral nervous system consists of nerves that form communication networks between the central nervous system and the body parts. It communicates signals (sensory and motor) that monitor our health and effect the changes in our brain and organ functions. In essence, the peripheral nervous system keeps us healthy. The program envisions to treat conditions such as post-traumatic stress disorder, inflammatory diseases, depression, and different parts of the body dealing with chronic pain (“Electrical Prescriptions.” 2016). Technologies created through this program should be able to detect onset of disease and automatically restore health in an individual by stimulating the corresponding part of the peripheral nerves as needed.

Researchers at Columbia University, Circuit Therapeutics, Florey Institute of Neuroscience and Mental Health, Johns Hopkins University, Massachusetts Institute of Technology, Purdue University and University of Texas are among that have been awarded
funds under this program. Some of the current funded projects under this program are focusing on:

a. Development of closed-loop neuromodulation (where one neuron uses chemicals to regulate another group of neurons) systems design that should be able to restore healthy physiological state in response to on-board physiological monitoring (“Electrical Prescriptions.” 2016).

b. Development of minimally and non-invasive technologies. Researchers are trying to understand the underlying mechanisms of ultrasound for neuromodulation (“Electrical Prescriptions.” 2016). Researchers aim to use ultrasound to provide intervention, including activation and inhibition of nerves.

c. A team of researchers is studying the use of vagal nerves (the tenth cranial nerve that interacts with the control of the heart, lungs and digestive tract) to induce new neural connections for treatment of post-traumatic stress disorder (“Electrical Prescriptions.” 2016). The researchers envision that the use of neural plasticity could potentially reduce stress and anxiety when presented with traumatic scenarios.

Summary of Agency-specific programs and their extramural funding institutes:

Table 5. Summary of DARPA- and NIH-funded programs chosen to be explored in this research study and the extramurally funded institutes that are utilizing the funding through these agencies for the BRAIN initiative.

<table>
<thead>
<tr>
<th>Agency</th>
<th>Program</th>
<th>Extramural Funded Institutes</th>
</tr>
</thead>
</table>
| NIH    | Next Generation Human Imagining | Vanderbilt University  
Massachusetts Institute of Technology  
University of Arizona  
Yale University  
University of Minnesota  
University of California |
| NIH    | Next Generation Human Invasive Devices | Massachusetts General Hospital  
Baylor School of Medicine  
Emory University  
Cleveland Clinic |
Interviews were conducted in person, via telephone, and/or via email if an individual did not have any other availability to meet. All participants provided informed consent prior to being interviewed.

Part II- In the second part of my study, I obtained data from the Pew Research Center for a survey that they conducted in 2014. The data was collected via survey to see how the general public in the United States feels about brain research and what their attitudes are towards obtaining a brain implant. Over 1000 adults were interviewed and their responses noted. I used the raw data from Pew Research Center to compare with the demographics and values of interviews that I conducted as part of this study to draw similarities and differences between the two demographics.

Part III- In the third part of my study, I reviewed the archival funding allocations for the President’s budget request vs. the appropriations bills passed by Congress for fiscal years 2014, 2015, and 2016, as well as agency reported actual budget utilization, per Government
Performance and Results Act (GPRA) mandate. Evaluating the budgets for the three years since the BRAIN initiative should potentially show a pattern in how funding is obligated federally and how it impacts funding obligations within an agency. Review of these documents will provide the fiscal scope (funding obligations by agency and federal research and development budget, towards neuro S&T research) and scale of the research and the number and distribution of research or applied research initiatives.

**Measurement Plan**

Methodological triangulation techniques were applied using a mixed-method methodology including interviews, survey databases, and archival record review. This way, not just one method is being used to collected data. If the findings from all of the methods draw the same similar conclusions, then validity and reliability in the findings will be established.

**Analysis Plan**

Used mixed methods to understand similarities and contradictions between quantitative and qualitative findings. This ensured that the findings are grounded in the study participant’s attitudes, values, and beliefs.

**Qualitative Analysis**

a. Conversation Analysis: the interviews with the Agencies and Researchers were conducted in person, via phone, or via email. Understanding speech patterns, especially pauses and hums before answering certain questions will allow us to understand the way participants view their interaction with the interviewer and the questions.

b. Selective Coding: based on the data collected, central core categories will be developed to understand if patterns emerged throughout the interview of the agency
personnel and the researchers between NIH and DARPA. The categories and their interrelationships will be combined to form an understanding of the BRAIN initiative, the influence of the initiatives on agencies, the resulting product, and the effect it has on the general public. This, in turn, will allow us to describe what is happening with neuro S&T research and its societal implications.

c. Normative Analysis

1. Axiology (focus on what public believes about neuro S&T research and the public interest);

2. Deontology (the initiative and the delegation to agencies; examine what the responsibilities of the government is in conceiving, supporting and disseminating neuro S&T research outcomes).

3. Archival Record Analysis: archival funding allocations for the President’s budget request vs. the appropriations bills passed by Congress for fiscal years 2014, 2015, and 2016, as well as agency reported actual budget utilization, per Government Performance and Results Act (GPRA) mandate. Evaluating the budgets for the three years since the BRAIN initiative started should potentially show a pattern in how funding is obligated federally and how it impacts funding obligations within an agency. Review of these documents will provide the fiscal scope (funding obligations by agency and federal research and development budget, towards neuro S&T research) and scale of the research and the number and distribution of research or applied research initiatives.

4. Stakeholder Analysis: to understand the roles and responsibilities of everyone affected by this initiative and what impact it has on the society at large.
Quantitative Analysis

Will be performed to analyze the fiscal scope (funding obligations by agency and federal research and development budget, towards neuro S&T research) and scale of the research and the number and distribution of research or applied research initiatives.

a. Pattern analysis: to see if there is a pattern in how funding is obligated federally and how it impacts funding obligations within an agency.
   1. Bar graphs
   2. Scatter plots

b. Compare and contrast demographics of agencies, researchers, and Pew Research survey data; to see if there are any commonalities in views or opinions based on the demographics obtained.

The methodological design and logic outlined in this chapter, should provide data that addresses the hypotheses and the central research questions of this study. In the next chapter, we will present the data gathered through the study design and analyze the data.
CHAPTER 4
RESULTS & ANALYSIS

As discussed in the methodology chapter, data were collected via three different instruments as part of this study, (1) interview with agency personnel, (2) secondary survey data collected by Pew Research Center, and (3) archival funding allocations. The data collection and findings from part I, II, and III gave us a holistic picture of neuro S&T research, specifically projects stemming from the BRAIN initiative. In this section (Results), the data will be presented. The analysis of the data will be conducted in the next section (Analysis).

Results:

In order to answer the proposed questions, the study was divided into three parts:

Part I- To conduct this study, I chose two programs from DARPA and NIH. Interviews were then conducted with agency personnel who were administrators, policy makers, and/or science/technology specialists at DARPA and NIH. The intentions of these interviews were to understand strategies for implementation of initiatives and allocation of funding in order to establish ethical and legal dimensions in public policies associated with neuro S&T research. Potentially 3-5 personnel per agency were interviewed, with at least one person in the capacity of administrator, one policy maker, and one S&T specialist. Data collected was used to test H₁, and H₂.

Along with institutional participants at DARPA and NIH, interviews were conducted with scientists and researchers involved in neuro S&T research. These interviews were to assist in establishing ethical and legal dimensions in public policies associated with neuro S&T research. Potentially 5-10 scientist and researchers were interviewed per agency, selected based on the programs that they were working on. The questionnaire that was used to interview the
personnel was approved by the University of Baltimore Institutional Review Board (IRB) in June 2016. Interviews were conducted in person, via telephone, or via email if an individual was unable to meet. All participants provided informed consented prior to being interviewed.

The two programs chosen from NIH were:

1. Next Generation Human Imaging
2. Next Generation Human Invasive Devices

The two programs chosen from DARPA were:

1. Hand Proprioception and Touch Interfaces (HAPTIX)
2. Electrical Prescriptions (ElectRx)

Part II- In the second part of my study, I obtained data from Pew Research Center for a survey that they conducted in 2014. The data was collected via survey to see how the general public in the United States feels about brain research and what their attitudes are towards obtaining a brain implant. Over 1000 adults were interviewed and their responses noted. I used the raw data from Pew Research Center to compare with the demographics and values of interviews that I conducted as part of this study to draw similarities and differences between the two demographics. Data collected assisted in testing $H_2$.

Part III- In the third part of my study, I reviewed the archival funding allocations for the President’s budget request vs. the appropriations bills passed by Congress, as well as GPRA mandated data provided via reports from agencies on the actual budget spent for fiscal years 2014, 2015, and 2016. Evaluating the budgets for the three years since the BRAIN initiative started should potentially show a pattern in how funding is obligated federally and how it impacts funding obligations within an agency. Review of these documents will provide the fiscal scope (funding obligations by agency and federal research and development budget,
towards neuro S&T research) and scale of the research and the number and distribution of research or applied research initiatives. Data collected assisted in testing $H_1$, $H_2$, and $H_3$.

**Limitations of Data Collection**

In interviewing the agency personnel in 2016, it was noticeable to see that most of the individuals that were instrumental in starting the BRAIN initiative had either already left their position or had transferred to other roles, due to the nature of their agencies. In 2017, when President Trump proposed his budget blueprint for the U.S. (“America First-A Budget Blueprint to Make America Great Again.” 2017), he proposed major changes, where science was not a priority for the new administration. President Trump, proposed an 18% budget cut for NIH, reducing its proposed overall budget to $25.9 billion (Zhang 2017), where in the previous years, NIH’s budget tended to remain in the $30.5-31.5 billion range. To date, the budget nor the President have specifically called out the BRAIN initiative, and whether funding will be provided or pulled out for the programs currently being funded through the initiative.

It should be noted that in conducting interviews at DARPA and NIH with the researchers and agency personnel, it became evident that the quantity of the individuals that participated did not/could not change the outcome, as most answers seemed to be grounded in the same theories of ethical, legal, and societal implications surrounding neuro S&T research. Therefore, the data collected through interviews with the selected participants can be used to make generalizations for DARPA and NIH as organizations.

In assessing the collected unweighted data samples from part II of the research study, the survey data collected by Pew Research Center shows that there is a 95% level of confidence for the different groups interviewed in the survey. This means that 95% of the interviewees met the parameters set by the researchers. Since the data was collected via interviews on the phone,
wording of the questions, tone of the interviewer, understanding of the interviewee, and surrounding environment of the interviewee at the time the interview is conducted, unintentional error can be introduced to the collected data in many ways.

Part I-Interviews

The data collected by the participants in this study was all anonymous, and no identifiers were collected. Only basic demographic information was collected from the participants. Data collected was kept on a secure network with access protection. Access was only available to the research investigator.

a. Interviews with Agency Personnel at DARPA and NIH

Individuals interviewed were selected based on purposive sampling based on their expertise in the field of neuro S&T. Agency personnel were interviewed who had experience in the capacity of administrator, policy maker, and S&T specialist in reference to their agency’s involvement and participation with the BRAIN initiative and neuro S&T in general. Interviews were conducted with agency personnel to understand strategies for implementation of initiatives and allocation of funding in order to establish ethical and legal dimensions in public policies associated with neuro S&T research. Agency personnel interviewed included government personnel and those contractors that were directly supporting the initiative as a subject matter expert. Data collection took place from July 2016 to August 2017.

Table 6. Agency Personnel Interviewed (July 2016-August 2017).

<table>
<thead>
<tr>
<th>BRAIN Initiative/Neuro S&amp;T Personnel</th>
<th>DARPA</th>
<th>NIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>S&amp;T specialist/administrator</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>S&amp;T specialist/policy maker</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td>6</td>
</tr>
</tbody>
</table>
Data collected from interviews with agency personnel were recorded and then transcribed from a professional service (Scribie.com). The interview transcripts were then reviewed and sent back to the individuals (interviewees) to ensure the accuracy of the transcription. The data was then manually sorted, categorized, and coded to see if any themes or patterns emerged. The three categories established based on the data review were participation, funding, and addressing societal views. The data collected is reported below:

1. Interview Responses with NIH Agency Personnel involved with BRAIN Initiative/Neuro S&T Research:

Table 7. Demographic Information for NIH Agency Personnel.

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age</th>
<th>Education</th>
<th>Ethnicity/Race</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M/F</td>
<td>30-49</td>
<td>65+</td>
</tr>
<tr>
<td>Male</td>
<td>5</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Female</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The interviews that were conducted with NIH agency personnel were sorted, categorized, and coded to see if any themes or patterns emerged. The three categories established based on the interview responses were participation, funding, and addressing societal views. Table 3 provides an overview of the categories and themes that emerged after the interviews were coded. The responses in detail are presented below:

- Participation

According to the interviewees, participation in the BRAIN initiative for NIH was in response to the Presidential BRAIN initiative in 2013. In response to this, NIH convened a working group of the Advisory Committee to the Director
(ACD) to develop a rigorous plan for achieving the scientific vision put forth by the BRAIN initiative. This working group sought broad input from the scientific community, patient advocates, and the general public. Their report, BRAIN 2025: A Scientific Vision, released in June 2014. The report articulated the scientific goals of the BRAIN Initiative and developed a multi-year scientific plan for achieving these goals, including timetables, milestones, and cost estimates. The BRAIN Initiative is funded through set-asides in congressional appropriation annually. This money is mandated for use on BRAIN initiative and is separate from money allocated and appropriate to individual institutes at NIH for their individual missions/goals. Therefore, participation in the BRAIN initiative was based on NIH’s mission, vision, funding allocation by the Office of Management and Budget (OMB), and direct involvement through the working groups involved with the BRAIN initiative.

Following the announcement of the BRAIN initiative, the involvement of NIH changed as the goals set forth by the President were ambitious and bold. The working group agreed that in its initial stages, the best way to enable these goals is to accelerate technology development. The focus is not on technology per se, but on the development and use of tools for acquiring fundamental insight about how the nervous system functions in health and disease. In addition, since this initiative is only one part of the NIH’s substantial investment in basic and translational neuroscience, these technologies are evaluated for their potential to accelerate and advance other areas of neuroscience as well.
In 2017, when the Presidential administration changed, the agency to date has not received guidance from the new administration on the BRAIN initiative. The new administration has not appointed a new Director to date, and therefore the agency is still operating on the same agenda for the BRAIN initiative as it was in the previous fiscal year.

- Funding

According to the agency personnel that were interviewed, funding for the BRAIN initiative at NIH is allocated keeping several different issues in mind. NIH funding is allocated/appropriate through congressional mandates annually. Money appropriated to NIH contains set-asides for each individual institute and for the BRAIN initiative. The BRAIN Initiative funding opportunities are developed and awarded using the guidance of the BRAIN 2025 Report. NIH staff supporting the BRAIN Initiative analyze proposals and progress/success of awarded projects to determine the exact pace for progressing through the goals of BRAIN. The main factors are analysis of ongoing activities, pre-existing needs, timing (which is how much funding is available relative to the end of the fiscal year and whether it is a single year or multi-year mandate). The relative need for the technology is especially considered and is assessed based on receipt of input from public workshops and requests for information through different channels. Therefore, the scientific needs/merit, technical needs/merit, opportunities (existing and anticipated), and availability of funds all play an integral role in figuring out how funding is allocated.

In 2017, when the Presidential administration changed, the agency to date has not received guidance from the new administration on the BRAIN initiative. The new administration has not appointed a new Director to date, and therefore the agency is still
operating on the same funding for the BRAIN initiative as it was in the previous fiscal year.

- Societal Views and Addressing those Views

Per the interviewees, societal views surrounding the BRAIN initiative, neuro S&T research are assessed and addressed within the agency and externally, based on each individual program. These can vary and change based on the program or technology being developed. Internally, discussions revolve around opportunity costs, to see how compelling are the arguments in favor of the research and what the potential risks are. Especially, when undertaking new research proposals in a particular area (disease related), how well justified is the selection; i.e., if choosing to support this and not another disease, what are the pros and cons of that? What existing programs might we have to terminate in order to support this? etc. Therefore, cost-benefit analysis and opportunity costs weight heavily on the types of decisions made. Potential barriers gives rise to issues surrounding the ethical, legal, and societal views surrounding neuro S&T research:

  i. Ethical issues are being addressed by NIH through utilizing internal and external ethical oversight. A specific Neuroethics Working Group (NWG) has been formed that is charged with helping anticipate and address new and unique ethical issues that the BRAIN research will generate.

  ii. Legal issues are being addressed by NIH through internal legal oversight of the general council. In addition, the NWG is co-chaired by a professor of law, who specializes in neurolaw and neuroethics.
iii. Societal views are being addressed through external and internal oversight to ensure unbiased enrollment/distribution does not occur. Every proposal is required to explicitly address what their plans are for ensuring appropriate representation for participants in their study. Typically, these proposals are reviewed by committees at the researcher’s organization, scientific review panel, and the NIH staff prior to being awarded funding.

Table 8. NIH Agency Personnel Interview Responses for BRAIN Initiative/Neuro S&T Research.

<table>
<thead>
<tr>
<th>Participation</th>
<th>Funding*</th>
<th>Addressing Societal Views</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mission</td>
<td>Congressional Mandate</td>
<td>Opportunity Costs</td>
</tr>
<tr>
<td>Vision</td>
<td>Availability of Funds</td>
<td>Cost-benefit Analysis</td>
</tr>
<tr>
<td>Presidential Initiative</td>
<td>Scientific Merit/Need</td>
<td>Ethical</td>
</tr>
<tr>
<td>- Direct Involvement</td>
<td></td>
<td>• External Institutional Review Boards</td>
</tr>
<tr>
<td>- OMB funding allocation</td>
<td></td>
<td>• Implementing Internal Ethical Oversight</td>
</tr>
<tr>
<td>Acceleration of Neuro S&amp;T due to BRAIN initiative</td>
<td>Technical Merit/Need</td>
<td>Legal</td>
</tr>
<tr>
<td>Acceleration of Development of Tools to Understand and Accelerate Translational Neuroscience</td>
<td>Opportunities (existing and anticipated)</td>
<td>Societal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• External Oversight to Ensure Unbiased Enrollment/Distribution</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Internal Oversight to Ensure Unbiased Enrollment/Distribution</td>
</tr>
</tbody>
</table>

*Funding refers to overall funding for neuro S&T research
2. Interview Responses with DARPA Agency Personnel involved with BRAIN Initiative/Neuro S&T Research:

Table 9. Demographic Information for DARPA Agency Personnel.

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age</th>
<th>Education</th>
<th>Ethnicity/Race</th>
</tr>
</thead>
<tbody>
<tr>
<td>M/F</td>
<td>30-49</td>
<td>50-64</td>
<td>Ph.D./M.D.</td>
</tr>
<tr>
<td>Male 4 3 1 4 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female 2 2 2 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total 6</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The interviews that were conducted with DARPA agency personnel were sorted, categorized, and coded to see if any themes or patterns emerged. The three categories established based on the interview responses were participation, funding, and addressing societal views. Table 5 provides an overview of the categories and themes that emerged after the interviews were coded. The responses in detail are being presented below:

- Participation

According to the interviewees, participation in the BRAIN initiative for DARPA was in response to the Presidential BRAIN initiative in 2013. DARPA was already conducting research and had several programs already involved in neuro S&T. Therefore, existing and planned programs ended up aligning with some of the goals set forth by the BRAIN initiative. The BRAIN Initiative is funded through set-asides in congressional appropriation annually. This money is mandated for use on the BRAIN initiative and is separate from money allocated and appropriated to other programs at DARPA for their individual missions/goals. Therefore, participation in the BRAIN initiative are based on DARPA’s mission, vision, and funding allocation by the Office of Management and Budget (OMB), and direct involvement through the working groups involved with the BRAIN initiative.
Following the announcement of the BRAIN initiative, the DARPA neuro S&T programs adopted a stronger focus on physiological mechanisms, during this same time a new office was stood up by DARPA, which focus specifically on Biological Technologies. DARPA’s focus is on technology development and use of tools for acquiring fundamental insight about how the nervous system functions. In addition, since this initiative is only one part of the DARPA’s substantial investment in basic and translational neuroscience, these technologies are evaluated for their potential to accelerate and advance other areas of neuroscience as well.

In 2017, when the Presidential administration changed, the agency to date has not received guidance from the new administration on the BRAIN initiative. The new administration has not appointed a new Director to date, and therefore the agency is still operating on the same agenda for the BRAIN initiative as it was in the previous fiscal year.

- Funding

Per the interviewees, funding for the BRAIN initiative at DARPA is allocated keeping several different issues in mind. DARPA funding is allocated/appropriated through congressional mandates annually. Money appropriated to DARPA contains set-asides for programs and for the BRAIN initiative. The BRAIN Initiative funding opportunities are developed and awarded using the guidance the DARPA Director, program managers and DARPA support staff. DARPA staff supporting the BRAIN Initiative analyze proposals and progress/success of awarded projects to determine the exact pace for progressing through the goals of BRAIN.
The main factors are analysis of ongoing activities, pre-existing needs, and timing (which is how much funding is available relative to the end of the fiscal year and whether it is a single year or multi-year mandate). The relative need for the technology is especially considered and is assessed based on receipt of input from public workshops and requests for information through different channels. In addition, funding decisions are based on potential impact. DARPA program managers always ask the question “how would the proposed technology leap ahead of the state of the art?” and “if successful, what difference will it make?” Therefore, overall, the scientific needs/merit, technical needs/merit, opportunities (existing and anticipated), and availability of funds, all play an integral role in figuring out how funding is allocated.

In 2017, when the Presidential administration changed, the agency to date has not received guidance from the new administration on the BRAIN initiative. The new administration has not appointed a new Director to date, and therefore the agency is still operating on the same funding for the BRAIN initiative as it was in the previous fiscal year.

- Societal Views and Addressing those Views

Per the interviewees, societal views surrounding the BRAIN initiative, neuro S&T research are assessed and addressed within the agency and externally, based on each individual program. These can vary and change based on the program or technology being developed. Potential barriers surrounding the BRAIN initiative, neuro S&T research are assessed and addressed within the agency and externally. Internally, program managers assume responsibility for evaluating and mitigating potential risks and barriers. In addition, the agency has a very strong moral compass to do what is right.
Proposed research is reviewed and resolution strategies for anticipated barriers are considered prior to approval of any proposal.

In addition, DARPA has established an Ethical, Legal, and Societal (ELSI) panel of external experts in the field of neuro S&T. The panel reviews and provides feedback on all DARPA-funded neuro S&T programs. They point out barriers to consider and suggest how the program manager could address the barriers. The ELSI panel input is considered by the program manager and leadership as they develop messaging and mitigation strategies. While informed by ELSI panel input, the Agency maintains autonomy for final decisions. Therefore, cost-benefit analysis and opportunity costs weight heavily on the types of decisions made. Potential barriers give rise to issues surrounding the ethical, legal, and societal views surrounding neuro S&T research:

i. Ethical issues are being addressed by DARPA through utilizing internal and external ethical oversight. An ELSI panel of external experts across each of the disciplines (ethics, legal, societal) provides insights and feedback on the Agency’s neuroscience programs.

ii. Legal issues are being addressed by DARPA through internal legal oversight of the general council. In addition, the ELSI panel has experts that specialize in neurolaw and neuroethics.

iii. Societal views are being addressed through external and internal oversight to ensure unbiased enrollment/distribution does not occur. Every proposal is required to explicitly address what their plans are for ensuring appropriate representation for participants in their study. Typically, these proposals are reviewed by committees at the researcher’s organization,
ELSI panel, and the DARPA staff prior to being awarded funding. In addition, DARPA programs work at a very quick pace. The goal is to have technologies transition quickly into commercial production for public distribution and use.
Table 10. DARPA Agency Personnel Responses for BRAIN Initiative/Neuro S&T Research.

<table>
<thead>
<tr>
<th>Participation</th>
<th>Funding*</th>
<th>Addressing Societal Views</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mission</td>
<td>Congressional Mandate</td>
<td>Opportunity Costs</td>
</tr>
<tr>
<td>Vision</td>
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<td>Scientific Merit/Need</td>
<td>Ethical</td>
</tr>
<tr>
<td>• Direct Involvement</td>
<td></td>
<td>• External Institutional Review Boards</td>
</tr>
<tr>
<td>• OMB funding allocation</td>
<td></td>
<td>• Implementing Internal Ethical Oversight</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Ethical, Legal, and Societal Panel</td>
</tr>
<tr>
<td>Acceleration of Neuro S&amp;T due to BRAIN initiative</td>
<td>Technical Merit/Need</td>
<td>Legal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Internal Legal Oversight (general council)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Ethical, Legal, and Societal Panel</td>
</tr>
<tr>
<td>Acceleration of Development of Tools to Understand and</td>
<td>Opportunities (existing</td>
<td>Societal</td>
</tr>
<tr>
<td>Accelerate Translational Neuroscience</td>
<td>and anticipated)/Potential Impact</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>• External Oversight to Ensure Unbiased Enrollment/Distribution</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Internal Oversight to Ensure Unbiased Enrollment/Distribution</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Ethical, Legal, and Societal Panel</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Quick transition to facilitate commercial production for</td>
</tr>
<tr>
<td></td>
<td></td>
<td>public distribution and use</td>
</tr>
</tbody>
</table>

*Funding refers to overall funding for neuro S&T research

b. Interviews with Researchers at DARPA and NIH

Individuals interviewed were selected based on purposive sampling based on their expertise in the field of neuro S&T research. Researchers were interviewed who were funded as extramural researchers by DARPA and NIH. These were not DARPA or NIH employees, but were funded externally by DARPA and NIH to conduct research at their respective organizations with funding provided by DARPA and NIH. The researchers were then selected based on the programs that they were conducting research under at DARPA and NIH.
The two programs chosen from NIH for interviews with researchers were:

1. Next Generation Human Imaging
2. Next Generation Human Invasive Devices

The two programs chosen from DARPA for interviews with researchers were:

1. Hand Proprioception and Touch Interfaces (HAPTIX)
2. Electrical Prescriptions (ElectRx)

These interviews were conducted to assist in establishing ethical and legal dimensions in public policies associated with neuro S&T research. Data collection took place from July 2016 to August 2017.

Table 11. Researchers Interviewed (July 2016- August 2017).

<table>
<thead>
<tr>
<th>BRAIN Initiative/Neuro S&amp;T Researchers</th>
<th>DARPA</th>
<th>NIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAPTIX</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>ElectRx</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Next Generation Human Imaging</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Next Generation Human Invasive Devices</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td>6</td>
</tr>
</tbody>
</table>

Data collected from interviews with researchers were recorded and then transcribed from a professional service (Scribie.com). The interview transcripts were then reviewed and sent back to the individuals (interviewees) to ensure the accuracy of the transcription. The data was then sorted, categorized, and coded to see if any themes or patterns emerged. The six categories established based on the data were ethical issues, legal issues, societal issues, addressing potential barriers, mitigation strategies, and research use by public. The data collected is reported below:

1. **NIH Researchers Interviewed involved with BRAIN Initiative/Neuro S&T Research**

   **Focus of Programs: Health and Disease Treatments**
Table 12. Demographic Information for NIH Researchers.

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age</th>
<th>Education</th>
<th>Ethnicity/Race</th>
</tr>
</thead>
<tbody>
<tr>
<td>M/F</td>
<td>30-49</td>
<td>50-64</td>
<td>Ph.D./M.D.</td>
</tr>
<tr>
<td>Male</td>
<td>6</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Female</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The interviews that were conducted with NIH-funded extramural researchers were sorted, categorized, and coded to see if any themes or patterns emerged. The six categories established based on the data were ethical issues, legal issues, societal issues, addressing societal views, mitigation strategies, and research use by public. Table 8 provides an overview of the categories and themes that emerged after the interviews were coded. The responses in detail are being presented below:

- Ethical Issues

Per the interviewees, the ethical issues that surround the two-programs selected from the NIH-funded BRAIN initiative are diverse and complex in nature. For example, with issues related to subjects with disorders of consciousness, ethical issues of civil rights and disability rights take center stage. These two fall broadly under the justice argument. The issue of autonomy also comes up especially in brain-computer interface concepts, where we are taking people who require, assistance with everything and potentially granting them the ability to, now, do some things for themselves that they otherwise couldn't. The goal of the research is, in many ways, to restore autonomy that has been produced as a result of neurologic disease or injury. It is more along the lines of improving or returning more towards normal, while not veering into augmentation. However, other programs do veer into the issue of augmentation. Therefore, overall the issues of autonomy, freedom, fairness, and augmentation are some of the most common ethical issues surrounding these research endeavors.
• Legal Issues

Based on the respondents, legal issues surrounding the NIH-funded BRAIN initiative programs stem from laws that are already governing us. These laws, when looked at in the light of the technologies and treatments being provided by the neuro S&T research, give rise to issues of justice and fairness. In addition, legal issues could rise from side effects that are not anticipated through use of a particular device or treatment. It gets to these sorts of fundamental questions of “Who?” Who is actually in control, and who is actually driving? The prosthetics are a good place to start, but that is not where these issues rise. That is only because it meets a need and that it is a pathway in, as perceptual integration starts to take hold. For the question of “who looks at?”, how do you actually define who? Questions of ownership and legality, and questions of ethics, intent, agency, and engagement, then become very nebulous. Who actually is the who? Is it the system? Is it the system's input? Is it the person who built the system that integrates with the person, even though the person believes that from a systems perspective, that they are a part of this larger system? So, it really gets down to the question of “Who”? and thus, makes it difficult to decide the culpability or responsibility of the individual. In summary, the legal issues surrounding these programs are diverse in nature depending on the nature of the treatment/technology, but are all in the realm of justice and fairness.

• Societal Issues/Needs

The researchers indicated that the societal issues and needs regarding these programs are still evolving. As these treatments and technologies are introduced into society and become mainstream, we will see how society deals with them; some of the issues that the researchers can foresee are fair and equal distribution, economical
accessibility, and equal treatment of participants by society. Some researchers believe that society is going to wake up and say, in retrospect, for individuals that were considered in a vegetative state, but were actually in a minimally conscious state: "Oh my God, I can't believe we treated these people (with brain illnesses) this way. People who were conscious and all". So, we are going to have to make space for these individuals in society. We will have to accommodate people who have covert consciences. That is a major societal implication of work with minimally conscious individuals and it can be generalized to children with autism as well.

Another potential issue may be the metrics by which we decide as a society that healthcare technologies have sufficient value to an individual to be reimbursed by our healthcare system. We do want to make sure that we do everything we can and that anybody who would need or benefit from these technologies can get access to them. They will never be inexpensive, but they need to be at a reasonable enough cost in terms of their production and maintenance that they are accessible to as many people who need them as possible. Another is access to beneficial technologies; that is the equal access to beneficial technologies, which is a financial and healthcare reimbursement-related kind of ethical/societal issue.

- Addressing Societal Views

Researchers involved in this work are very cautious about ensuring that all barriers that are foreseen based on their work are addressed and resolved as soon as possible. All of the research that was funded by NIH to support the BRAIN initiative goes through rigorous review and oversight. The funded researchers have to obtain approvals from their local IRBs and NIH IRB, and work with their Neuroethics Working
The researchers interviewed, either personally or through their organizations, had mitigation strategies to address the ethical, legal, and societal issues being raised through their research. They want to work to address them prior to public release of their technology/treatment to ensure that the general public is accepting of the research. From inception of an idea to execution, researchers are thinking about how to proceed forward depending on who the stakeholders are and who the end users will be. Those decisions are made and thought about very actively during the very initial stages. Most researchers have an essentially open-door policy to any oversight. They could have a site visit from the FDA, Joint Interface Control Office (JICO), funding organization, reviewing IRB or Institutional Animal Care and Use Committee (IACUC). Anyone of these large stakeholders could come into the lab at any time for review of records or research documents and the researchers make them available.

Another mitigation strategy is a rigorous consent process. In some cases, consent process is months-long in terms of initial discussions, descriptions of the study, and conversations about how the study rolls out, what the surgical components are, etc. Researchers are also cautioned to speak to media about research that has not been peer reviewed. Sharing of information prior to it being at least vetted externally amongst another group of experts can quite often be counter-productive because what is being
shared either is not true or can be considerably over-represented in the press. That is
where, as a field, neuro S&T can get into trouble. In addition, researchers suggest, as a
rule, to only speak about what they are trained to talk about. If a question delves into
something that is not their specialty, then make reference to someone who can best
answer. The worst thing you can do is state something that is inaccurate or that has not
been peer reviewed. Avoid hyperbole at all costs.

- Research Use by Public

Finally, when the researchers were asked their opinion on whether they think
neuro S&T will face resistance by the general public, their answers all veered in the same
direction: “it depends”. Researchers recommend that there has to be open dialogue
between the patients or their representatives, the end users (people who will potentially
benefit from these developments), the people who are developing them, and the
intermediaries (who, in the case of medical devices, are surgeons who would be
implanting them). If this is done, then the structure does impose much higher barriers to
adoption compared to less invasive therapies or less invasive options. This dialogue and
discussion will cause the researchers to have a built-in barrier, within their research,
which will prove vitally important to mitigation and acceptance of these
technologies/treatments. We have to elevate the scientific literacy and improve people's
ability to make judgements about what should be done and what should be funded. If
researchers ensure that their work is well-vetted and peer reviewed prior to releasing the
results, the acceptance will be highly likely and will face less apprehension.
Table 13. NIH-Funded Extramural Researcher Responses for BRAIN Initiative/Neuro S&T Research in programs: Next Generation Human Imaging and Next Generation Human Invasive Devices.

<table>
<thead>
<tr>
<th>Ethical Issues</th>
<th>Legal Issues</th>
<th>Societal Needs/Views</th>
<th>Addressing Societal Views</th>
<th>Mitigation Strategies</th>
<th>Research Use by the Public</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autonomy</td>
<td>Fairness</td>
<td>Equal distribution</td>
<td>Internally (research team)</td>
<td>Transparency in research</td>
<td>Depends on treatment</td>
</tr>
<tr>
<td>Fairness</td>
<td>Justice</td>
<td>Fair distribution</td>
<td>Externally (subject matter experts)</td>
<td>Involve stakeholders from beginning to end</td>
<td>Depends on how it is introduced</td>
</tr>
<tr>
<td>Augmentation</td>
<td>Who is in control?</td>
<td>Insurance coverage</td>
<td>IRB (internal or external)</td>
<td>Rigorous consent process</td>
<td>Perception vs reality</td>
</tr>
<tr>
<td>Freedom</td>
<td>Unintentional legal consequences</td>
<td>Economical accessibility</td>
<td>Data safety monitoring boards</td>
<td>Publish/media release peer reviewed neuro S&amp;T research</td>
<td>Risk vs benefit</td>
</tr>
<tr>
<td></td>
<td>Individual vs. authorized enrollment</td>
<td>Neuroethics Working Groups</td>
<td>Training</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. DARPA Researchers Interviewed involved with BRAIN Initiative/Neuro S&T Research

Focus of Programs: Treatments through Technological Advances

Table 14. Demographic Information for DARPA Researchers.

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age</th>
<th>Education</th>
<th>Ethnicity/Race</th>
</tr>
</thead>
<tbody>
<tr>
<td>M/F</td>
<td>30-49</td>
<td>50-64</td>
<td>Ph.D./M.D.</td>
</tr>
<tr>
<td>Male</td>
<td>6</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Female</td>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>6</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

The interviews that were conducted with DARPA-funded extramural researchers were sorted, categorized, and coded to see if any themes or patterns emerged. The six categories established based on the data were ethical issues, legal issues, societal issues, addressing societal views, mitigation strategies, and research use by public. Table 10
provides an overview of the categories and themes that emerged after the interviews were coded. The responses in detail are being presented below:

• Ethical Issues

Per researchers, the ethical issues that surround the two-program selected from the DARPA-funded BRAIN initiative are diverse and complex in nature. As the experiments become more complex and invasive, the level of expectation that risk vs benefit must rise. Essentially, the researcher must internally justify the risk/benefit ratio for an experiment. The primary ethical challenge will focus on augmentation of human performance. Currently, research is geared towards rehabilitation purposes, which leads to issues of autonomy, freedom and fairness. However, as these technologies progress, there is the real possibility that we will eventually develop prosthetic systems that are capable of enhancing normal human performance. Especially, when technology becomes mainstream and those that wish to “enhance” and can afford to can potentially affect the rich/poor divide.

Also, issues related to subjects with disorders of consciousness, ethical issues of civil rights and disability rights take center stage. The issue of autonomy also comes up especially in brain-computer interface concepts, where we are taking people who require, assistance with everything and potentially granting them the ability to, now, do some things for themselves that they otherwise could not. Therefore, the issues of autonomy, freedom, fairness, and augmentation are some of the most common ethical issues surrounding these research endeavors.

• Legal issues
According to the interviewees, the legal issues surrounding the DARPA-funded BRAIN initiative programs stem from laws that are already governing us. These laws, when looked at in the light of the technologies and treatments being provided by the neuro S&T research, give rise to issues of justice and fairness. In terms of the issues of justice and fairness, it seems appropriate that research participants deserve to be looked after from a medical perspective for health care and associated costs that result from their implanted devices. In counties with socialized or single-payer health care, this could be less problematic, but in the United States, this is an issue.

In addition, legal issues could rise from side effects that are not anticipated through use of a particular device or treatment. It gets to these sorts of fundamental questions of “who”? Who is actually in control, and who is actually driving? The prosthetics are a good place to start, but that is not where these issues rise. That's only because it meets a need and that it's a pathway in, as perceptual integration starts to take hold. For the question of “who looks at?”, how do you physically define who? Questions of ownership and legality, and questions of ethics, intent, agency, and engagement, then become very nebulous. In summary, the legal issues surrounding these programs are diverse in nature depending on the nature of the treatment/technology, but are all in the realm of justice and fairness.

- Societal Issues/Needs

Researchers interviewed believe that the societal issues and need regarding these programs are still evolving. As these treatments and technologies are introduced into society and become mainstream, we will see how society deals with them. Some of the
issues that the researchers can foresee are fair and equal distribution, economical accessibility, and equal treatment of participants by society. The societal implications of neuroprosthetics and advanced medical technologies in general can perhaps be divided into several categories. At what point should these devices be made available to the public, and how is this determined? Assuming that these devices will be expensive, who will have access to these devices? Will these technologies provide an advantage (or disadvantage) to individuals compared to their peers without the technology, and how will these differences be viewed? Current devices face significant barriers to deployment in the general public. To date, these devices have often provided insufficient function to really be considered useful, and advanced prosthetic devices have a high abandonment rate by users. However, as device technologies improve and become implantable, it is not clear who eventually should make the determination about the availability of these devices.

There are clear regulatory issues that must be dealt with in order to make a product ready for market, but once that is completed, it does not mean that devices are generally accessible. The cost and reimbursement for such devices is another barrier to wide deployment. Those that can afford devices are less subject to these restrictions, but often people that could benefit from devices are unable to afford them. A framework for determining the level of ability that a new device must provide so that insurance companies, etc., will provide the device does not yet exist. To this end, the payers can ultimately be the group that decides whether a technology is provided to people that can benefit from it. The cost of devices limits their impact. This is true both with a country like the United States, but also worldwide. There are several organizations that are
striving to provide low-cost prosthetics around the world in markets where a few hundred dollars is at the extreme end of affordability. This is in contrast to advanced implantable neuroprosthetics where a complete system might cost several hundred thousand dollars currently. Expensive technology tends to be adopted by those that can afford it first, which then makes it more affordable in the future. This model also exists in healthcare, but the question remains about whether this is in fact the right way for it to be. In the realm of neuroprosthetics, there exists the possibility for there to be the “haves” and the “have nots”.

• Addressing Societal Views

Researchers involved in this work are very cautious about ensuring that all barriers that are foreseen based on their work are addressed and resolved as soon as possible. Research with human subjects is heavily regulated. These regulatory bodies, including the FDA, local IRB, and potentially outside IRBs such as the Department of Defense IRBs, review every aspect of studies from recruitment methods and screening language through to study procedures and follow-up care. This provides the most rigorous way to assess proposed research studies. Typically, interaction between the regulators and researchers occurs and is a way to resolve differences to arrive at a final study protocol. These protocols are occasionally audited. It is however up to the researchers to comply with the agreed upon protocol and to report deviations or adverse events.

Researchers believe that the study investigator must be sure that any proposed risk is accompanied by sufficient benefit (to the subject, or in terms of research data acquired) to justify the study. This internal barrier is critical in the ethical considerations of the
researcher. Working in a multi-investigator environment can provide an opportunity to discuss these risk-benefit ratios that are ultimately the determinant of whether a particular research study is proposed to an external regulator.

• Mitigation Strategies

The researchers interviewed, either personally or through their organizations, had mitigation strategies to address the ethical, legal, and societal issues being raised through their research. They want to work to address them prior to public release of their technology/treatment to ensure that the general public is accepting of the research. From inception of an idea to execution, researchers are thinking about how to proceed forward depending on who the stakeholders are and who the end users will be. Those decisions are made and thought about very actively during the very initial stages. Education is key to avoiding backlash, fear, and conspiracy theories in the general public. Overpromising is counterproductive; results should be stated as is and not stated with what could potentially be reached one day.

Voluntary adoption of technology is critical. The deaf community was initially resistant to cochlear implants. Any law requiring parents to restore hearing to their deaf children would have been a mistake. Medical choices should be made by patients (and their caregivers) in consultation with their physician(s). These issues need informed discussion that includes the scientists, engineers, and technologists developing the systems, regulatory bodies who help manage and regulate deployment at a systems level, physicians and therapists who would be responsible for providing these technologies directly to users, end users of the technologies, and importantly, insurers who would need to make decisions about supporting these technologies. Careful thoughtfulness and
making clear efforts to ensure that the technologies are mindfully developed will go a long way towards addressing and mitigating many of the key barriers to effectively helping the end users.

- Research Use by the Public

Finally, when the researchers were asked their opinion on whether they think neuro S&T will face resistance by the general public, their answers all veered in the same direction: “it depends”. Researchers believe that the majority of the public will generally embrace technology as it relates to neuroscience. This is even true of invasive, implantable systems. In many areas, the general public are very quick to embrace new technologies, and researchers see no reason that this will not extend to neuroscience and prosthetics. Any apparent resistance to advanced prosthetics to date likely has far more to do with their generally poor functionality as opposed to a resistance to the idea of the technology itself. This is true for neural prosthetics as they are used for treating disease and injury. However, researchers do anticipate significant backlash to neuroprosthetics for augmentation, and this is an area where the research community should tread carefully.

Acceptance of new treatments for serious psychiatric conditions will depend on public awareness that psychiatric conditions are medical conditions and reflect real problems in the brain. It is not clear how the public will view new technologies to improve learning. People like the idea of saving time, but they expect that there will be no “free lunch” and will worry about side effects and unintended societal consequences. The public perception will likely mirror that of other performance-enhancing products. Better nutrition and training is embraced, while doping and steroids are shunned. Most
researchers believe that there is certain to be some vocal resistance to any new
technologies, but as long as the medical community is on board, acceptance will become
widespread overtime.

Table 15. DARPA-Funded Researcher Responses for BRAIN Initiative/Neuro S&T Research in
programs: Hand Proprioception and Touch Interfaces and Electrical Prescriptions.

<table>
<thead>
<tr>
<th>Ethical Issues</th>
<th>Legal Issues</th>
<th>Societal Needs/Views</th>
<th>Addressing Societal Views</th>
<th>Mitigation Strategies</th>
<th>Research Use by the Public</th>
</tr>
</thead>
<tbody>
<tr>
<td>Autonomy</td>
<td>Fairness</td>
<td>Equal distribution</td>
<td>Internally (research team)</td>
<td>Transparency in research</td>
<td>Depends on treatment</td>
</tr>
<tr>
<td>Fairness</td>
<td>Justice</td>
<td>Fair distribution</td>
<td>Externally (subject matter experts)</td>
<td>Involve stakeholders from beginning to end</td>
<td>Depends on how it is introduced</td>
</tr>
</tbody>
</table>

Enhance human performance; increase in rich/poor divide

Who is in control? Insurance coverage IRB (internal or external) Rigorous consent process Perception vs reality

Freedom
- Civil rights
- Disability rights

Unintentional legal consequences Economical accessibility Data safety monitoring boards Publish/media release peer reviewed neuro S&T research Risk vs benefit

Augmentation

Individual vs. authorized enrollment High technology cost ELSI Panel Training Abuse of technology

Part II-Survey Data

The previous section (part I) presented data that was collected from agency personnel and extramural researchers at DARPA and NIH involved with neuro S&T, stemming from the BRAIN initiative. Next, we will explore secondary data (part II), collected by Pew Research Center, to understand how the general public feels about using specific neuro S&T research treatments.

- Data Source
The data being analyzed in this study was gathered from a survey conducted by the Pew researchers. In 2014, 1,001 adults were interviewed via a survey questionnaire in either English and Spanish. The adults interviewed were 18 years or older, male or female, and were all living in the United States at the time of the interview. The interviews were conducted via phone (cell phone or landline) and the numbers were picked via random digital samples. Interviews were conducted by individuals at the Princeton Data Source. The gathered data of cell phone and landline interviews was then weighted using iterative techniques from the 2012 Census Bureau’s American Community Survey as well as the 2013 National Health Interview Survey.

- Descriptive Statistics of the Surveyed Population:

Conducting descriptive statistics on the surveyed population gave us a real picture of what the population’s demographics were. Of the 3,267 individuals surveyed, approximately 49% were male and 51% were female. Of the males in the population, the highest number of individuals were white, between the ages of 18-29, and with an education of high school or less. Of the females in the population, the highest number of individuals were black, over 65 of age, and with some college education completed. However, we must note that in analyzing the demographics, the percentages did not vary too far with +/- difference of 5% within the different criterions assessed. Therefore, it is safe to assume that the data is based on survey of a complete population across the U.S. of males and females, from all ethnicities, ranging from 18-65+ in age, and education from less than high school to college graduate or more (see table 16 below).

<table>
<thead>
<tr>
<th>Sex</th>
<th>Race/Ethnicity</th>
<th>Age</th>
<th>Education</th>
</tr>
</thead>
<tbody>
<tr>
<td>M/F</td>
<td>White</td>
<td>Black</td>
<td>Non-White (incl. Hispanic)</td>
</tr>
<tr>
<td>1602</td>
<td>1048</td>
<td>166</td>
<td>518</td>
</tr>
<tr>
<td>49%</td>
<td>32%</td>
<td>5%</td>
<td>16%</td>
</tr>
<tr>
<td>1665</td>
<td>1068</td>
<td>215</td>
<td>577</td>
</tr>
<tr>
<td>51%</td>
<td>33%</td>
<td>6%</td>
<td>18%</td>
</tr>
<tr>
<td>Total</td>
<td>3267</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

Next, we conducted a frequency distribution on the dependent variable, which was to evaluate the responses of the individuals surveyed on the question: “would you personally do this-get a brain implant to improve your memory or mental capacity?” Out of the 3,267 individuals surveyed, 848 individuals said yes, 2,357 said no, and 62 answered don’t know or refused to answer this question. Therefore, in this population, individuals would rather not get a brain implant (72.1%), even if it means that they would have a better memory or mental capacity resulting from the procedure.

Table 17. Frequency Distribution of the Dependent Variable from the Secondary Data collected via Survey by Pew Research Center.

<table>
<thead>
<tr>
<th>Would you get a brain implant?</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>848</td>
</tr>
<tr>
<td></td>
<td>26.0%</td>
</tr>
<tr>
<td>No</td>
<td>2357</td>
</tr>
<tr>
<td></td>
<td>72.1%</td>
</tr>
<tr>
<td>Don’t Know</td>
<td>62</td>
</tr>
<tr>
<td></td>
<td>1.9%</td>
</tr>
<tr>
<td>Total</td>
<td>3267</td>
</tr>
<tr>
<td></td>
<td>100%</td>
</tr>
</tbody>
</table>

Cross-tabular analysis of the Dependent and Independent variables

1. Religion
In assessing the impact of an individual’s religion on whether or not they would want to get a brain implant to improve their memory or mental capacity, we ran a cross-tabulation analysis on the population surveyed. The cross-tabulation analysis was run only on those individuals that either answered yes or no; the individuals that answered don’t know or refused to answer were marked as unknown in the analysis test. Within the population, the highest percentage of individuals surveyed were Christians and the lowest number of individuals were Hindus. In assessing the responses, individuals that identified themselves as having a religious preference more frequently answered no to obtaining a brain implant: specifically, those self-identifying as Christians (74.7%), Jewish (66%), Muslim (86.2%), Buddhist (66.7%) and Hindu (50%) answered no. However, out of all the categories, the highest number of individuals to say yes to obtaining a brain implant within a group were those that have identified themselves as having a Hindu religious affiliation.

<table>
<thead>
<tr>
<th></th>
<th>Christianity</th>
<th>Jewish</th>
<th>Muslim</th>
<th>Buddhist</th>
<th>Hindu</th>
<th>No Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>589 (25.3%)</td>
<td>18 (34.0%)</td>
<td>4 (13.8%)</td>
<td>8 (33.3%)</td>
<td>7 (50.0%)</td>
<td>0</td>
</tr>
<tr>
<td>No</td>
<td>1741 (74.7%)</td>
<td>35 (66.0%)</td>
<td>25 (86.2%)</td>
<td>16 (66.7%)</td>
<td>7 (50.0%)</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>2330 (100%)</td>
<td>53 (100%)</td>
<td>29 (100%)</td>
<td>24 (100%)</td>
<td>14 (100%)</td>
<td>0</td>
</tr>
</tbody>
</table>

2. Education

In assessing the impact of an individual’s level of education on whether or not they would want to get a brain implant to improve their memory or mental capacity, we ran a cross-tabulation analysis on the population surveyed. The
cross-tabulation analysis was run only on those individuals that either answered yes or no; the individuals that answered don’t know or refused to answer were marked as unknown in the analysis test. Within the population, the highest percentage of individuals surveyed were those that had completed high school and the lowest number of individuals were those that had completed less than high school. In assessing the responses, within the groups, of those individuals that had completed less than high school, 64% said no; in the category for high school, 78% said no; college, 80.7% said no; bachelor’s degree, 63.5% said no; and of those that had completed postgraduate or above, 60.2% said no. Therefore, in all categories, a higher percentage said no compared to those that said yes. However, out of all the categories, the highest number of individuals to say yes to obtaining a brain implant within a group were those that have completed postgraduate education or above.


<table>
<thead>
<tr>
<th></th>
<th>Less than High School</th>
<th>High School</th>
<th>Some College</th>
<th>Bachelor’s Degree</th>
<th>Postgrad or Above</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Yes</strong></td>
<td>54</td>
<td>254</td>
<td>192</td>
<td>184</td>
<td>146</td>
</tr>
<tr>
<td></td>
<td>36.0%</td>
<td>22.0%</td>
<td>19.3%</td>
<td>36.5%</td>
<td>39.8%</td>
</tr>
<tr>
<td><strong>No</strong></td>
<td>96</td>
<td>899</td>
<td>805</td>
<td>320</td>
<td>221</td>
</tr>
<tr>
<td></td>
<td>64.0%</td>
<td>78.0%</td>
<td>80.7%</td>
<td>63.5%</td>
<td>60.2%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>150</td>
<td>1153</td>
<td>997</td>
<td>504</td>
<td>367</td>
</tr>
<tr>
<td></td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>

3. Age

In assessing the impact of an individual’s age on whether or not they would want to get a brain implant to improve their memory or mental capacity, we ran a cross-tabulation analysis on the population surveyed. The cross-tabulation analysis was run only on those individuals that either answered yes or no; the individuals that answered don’t know or
refused to answer were marked as unknown in the analysis test. Within the population, the highest percentage of individuals surveyed were those in the age group of 30-49 and the lowest number of individuals were those that were in the age group of 65 and over.

In assessing the responses, within the groups, those individuals that were in the age group 18-29 77.4% said no; in the age group of 30-49, 76% said no; aged 50-64, 69.3% said no; and aged 65 or over, 71.2% said no to obtain a brain implant to improve their mental capacity or memory. Therefore, in all categories, a higher percentage said no compared to those that said yes. However, out of all the categories, the highest number of individuals to say yes to obtaining a brain implant within a group were those that were in the group aged 50-64 years.


<table>
<thead>
<tr>
<th></th>
<th>18-29</th>
<th>30-49</th>
<th>50-64</th>
<th>65+</th>
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<tbody>
<tr>
<td>Yes</td>
<td>149</td>
<td>251</td>
<td>263</td>
<td>185</td>
</tr>
<tr>
<td></td>
<td>22.6%</td>
<td>24.0%</td>
<td>30.7%</td>
<td>28.8%</td>
</tr>
<tr>
<td>No</td>
<td>511</td>
<td>793</td>
<td>595</td>
<td>458</td>
</tr>
<tr>
<td></td>
<td>77.4%</td>
<td>76.0%</td>
<td>69.3%</td>
<td>71.2%</td>
</tr>
<tr>
<td>Total</td>
<td>660</td>
<td>1044</td>
<td>858</td>
<td>643</td>
</tr>
<tr>
<td></td>
<td>100%</td>
<td>100%</td>
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</table>

Part III- Archival Funding Allocations from Congressional and Presidential funding allocations

In Part I, we presented data that was collected from agency personnel and extramural researchers at DARPA and NIH involved with neuro S&T, stemming from the BRAIN initiative. In part II, we explored secondary data, collected by Pew Research Center, to understand how the general public feels about using specific neuro S&T research treatments. In this section, we will be reviewing archival funding allocations as requested by the President and appropriated by Congress for the BRAIN initiative as well as the GPRA mandated reports by agencies on actual funding spent.
As proposed, I reviewed the archival funding allocations for the President’s budget request vs. the appropriations bills passed by Congress and the GPRA mandated reporting of actual funding spent for fiscal years 2014, 2015, and 2016 for NIH and DARPA. Evaluating the budgets for the three years since the BRAIN initiative started should potentially show a pattern in how funding is obligated federally and how it impacts funding obligations within an agency. Review of these documents will provide the fiscal scope (funding obligations by agency and federal research and development budget, towards neuro S&T research) and scale of the research and the number and distribution of research or applied research initiatives.

- **2014**

In 2014, $142.773 billion were requested by the President for R&D, from which $133.682 billion were allocated towards budgeting (Sargent 2013). The budget saw a $1.953 billion increase from FY 2013. Below is an overview of how the R&D Budget was distributed:

![FY 2014 R&D Budget Spending](image)

Figure 4. Fiscal year 2014, budget spending per the congressional appropriations for the research and development funding per department.

Per the President’s budget request, most of the institutes and centers would receive increases of about 1% compared to FY 2012 and about 7% compared to the FY 2013 operating
level, with selected exceptions reflecting program priorities. The Senate committee largely supported the Administration’s priorities, with a few variations. NIH and DARPA showed emphasis for FY 2014 on the BRAIN initiative, in order to develop tools for the study of complex brain functions.

NIH was appropriated $30.151 billion in funding by Congress for FY 2014, while the President requested $31.331 billion. Per GPRA mandated NIH budget report, $29.926 billion was the actual spent amount in FY2014. Out of which, $40 million was dedicated to just BRAIN initiative-specified research.

Figure 5. Fiscal year 2014, actual funding utilized vs. the BRAIN initiative specific budget for NIH (in billions).

As published in NIH’s FY 2014 congressional justification for budget:

“In FY 2014, NIH will begin its support of the Brain Research through Application of Innovative Neurotechnologies (BRAIN) Initiative, in order to develop a deeper understanding of brain function through the creation of new tools capable of examining the activity of the millions of nerve cells, networks, and pathways in the brain in real time. By measuring activity at the scale of circuits and networks in living organisms, we can begin to translate data into models that will decode sensory experience, motor planning, and, potentially, even memory, emotion, and thought. NIH is embracing a collaborative approach in tackling this challenge, working with researchers from across
the country, industry, foundations, and other government agencies including the Defense Advanced Research Projects Agency and the National Science Foundation. Successful completion of the BRAIN Initiative could revolutionize the field of neuroscience and set the stage for major advances in diseases such as Alzheimer’s, Parkinson’s, autism, schizophrenia, depression, and epilepsy. ” (“Department of Health and Human Services, National Institute of Health-FY2014 Budget.” 2014)

DARPA was appropriated $2.75 billion in funding by Congress for FY 2014, while the President requested $2.86 billion. Per GPRA mandated DARPA budget report, $2.752 billion was the actual spent amount in FY2014. Out of which, $38 million was dedicated to just BRAIN initiative- specified research.

Figure 6. Fiscal year 2014, actual funding utilized vs. the BRAIN initiative specific budget for DARPA (in billions).

As published in the CCCC Blog (Underwood 2013), DARPA for FY 2014 announced two programs as part of the BRAIN initiative, SUBNETS (Systems-Based Neurotechnology for Emerging Therapies) and RAM (Restoring Active Memory). As per the solicitations for the program, SUBNETS:

“DARPA seeks to develop a new understanding of complex, systems-based disorders of the brain. A major goal of this effort is to deliver a platform technology for precise
therapy in humans living with neuropsychiatric and neurologic disease, including veterans and active duty soldiers suffering from mental health issues. Methods developed through this program will use neural recording and stimulation to close the loop on therapeutic treatment in individuals who receive minimal benefits from currently available treatments. This program could lead to improved knowledge of multiple neural subnetworks of the brain that are involved in disease and illness.” (Underwood 2013)

RAM’s solicitation was:

“DARPA seeks new methods for analysis and decoding of neural signals in order to understand how neural stimulation could be applied to facilitate recovery of memory encoding following brain injury. Ultimately, it is desired to develop a prototype implantable neural device that enables recovery of memory in a human clinical population.” (Underwood 2013)

- 2015

In 2015, $135.352 billion were requested by the President to be allocated for the R&D budgeting (Sargent 2015). The budget saw a $1.670 billion increase from FY 2014. Below is an overview of how the R&D budget was distributed:

![Figure 7. Fiscal year 2015, budget spending per the congressional appropriations for the research and development funding per department.](image)

The President’s budget sought $135.352 billion for R&D in FY 2015, a 1.2% increase over the estimated FY 2014 R&D funding level of $133.682 billion. Congress completed
appropriations actions for most federal agencies through enactment of the Consolidated and Further Continuing Appropriations Act 2015, which was signed into law on December 16, 2014. NIH was appropriated $30.362 billion in funding by Congress for FY 2015, while the President requested $30.4 billion. Per GPRA mandated NIH budget report, $30.311 billion was the actual spent amount in FY2015. Out of which, $100 million was dedicated to just BRAIN initiative-specified research.

Figure 8. Fiscal year 2015, actual funding utilized vs. the BRAIN initiative-specific budget for NIH (in billions).

As published in NIH’s FY 2015 congressional justification for budget:

“The FY 2015 Budget includes $100 million for the BRAIN Initiative, an increase of $60 million over FY 2014, to ramp up activities in the second year. This bold multi-agency initiative requires ideas from the best scientists and engineers across many diverse disciplines and sectors. The BRAIN Initiative will build on the rapidly growing scientific foundation of neuroscience, genetics, physics, engineering, informatics, nanoscience, chemistry, mathematics, and technological advances of the past few decades to catalyze an interdisciplinary effort of unprecedented scope.” (“Obama Administration Proposes Doubling Support for the BRAIN Initiative.” 2015)

NIH programs are focusing on:

“Building a new arsenal of tools and technologies for studying the brain. This state-of-
the-art “toolbox” will include a systematic inventory of all the different types of cells in the brain, targeted genetic and non-genetic approaches for accessing specific cells and circuits, new and better capabilities for recording from rapidly firing collections of neurons, and interdisciplinary approaches to understanding how brain circuits produce unique human functions. NIH is also charting the course for the next generation of non-invasive imaging techniques that can be used to explore human brain functions and behaviors in real time.” (“Obama Administration Proposes Doubling Support for the BRAIN Initiative.” 2015)

DARPA was appropriated $2.87 billion in funding by Congress for FY 2015, while the President requested $2.91 billion. Per GPRA mandated DARPA budget report, $2.915 billion was the actual spent amount in FY2015. Out of which, $80 million was dedicated to just BRAIN initiative-specified research.

![DARPA R&D Funding FY 2015](image)

Figure 9. Fiscal year 2015, actual funding utilized vs. the BRAIN initiative-specific budget for DARPA (in billions).

As published by the White House BRAIN initiative propositions:

“In FY 2015, DARPA plans to invest an estimated $80 million to support The BRAIN Initiative. DARPA’s investments aim to leverage brain-function 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’ ability to understand the brain by fostering advancements in data handling, imaging, and advanced analytics.” (“Obama Administration Proposes Doubling Support for the BRAIN Initiative.” 2015)

DARPA’s BRAIN initiative-funded programs will:
“Create interfaces for handling and analyzing large datasets of neural data, allowing investigators to rapidly and transparently solve complex problems of computation, generate new models, and model the brain in multiple dimensions and spatiotemporal scales. New military medical imaging efforts will provide new discovery tools capable of understanding structures of the behaving brain at high resolution in a stable manner over multiple experiments and generate tremendous amounts of data regarding the functional and structural connections between regions of the brain. Finally, the Prosthetic Hand Proprioception and Touch Interfaces (HAPTIX) effort will develop human-ready implantable electronic microsystems that monitor and modulate information in motor and sensory fibers of peripheral nerves, enabling amputees to achieve advanced and intuitive control and sensory functions with prosthetic limbs.” (“Obama Administration Proposes Doubling Support for the BRAIN Initiative.” 2015)

- 2016

In 2016, $145.694 billion were requested by the President to be allocated for the R&D budgeting (Sargent 2016). The budget saw an increase of $7.625 billion (5.5%) over the estimated FY 2015 R&D funding level of $138.069 billion. Below is an overview of how the R&D budget was distributed:

**FY 2016 R&D Budget Spending**

- Department of Defense 49.50%
- Department of Health and Human Services 7.90%
- National Aeronautics and Space Administration 8.60%
- Department of Energy 8.40%
- National Science Foundation 4.30%
- Other 21.30%

Figure 10. Fiscal year 2016, budget spending per the congressional appropriations for the research and development funding per department.

The President’s budget proposed $145.694 billion for R&D in FY 2016, an increase of $7.625 billion (5.5%) over the estimated FY 2015 R&D funding level of $138.069 billion.
NIH was appropriated $31.311 billion in funding by Congress for FY 2015, while the President requested $32.311 billion. Per GPRA mandated NIH budget report, $31.381 billion was the actual spent amount in FY2016. Out of which, $135 million was dedicated to just BRAIN initiative-specified research.

![NIH R&D Funding FY 2016](image)

Figure 11. Fiscal year 2016, actual funding utilized vs. the BRAIN initiative-specific budget for NIH (in billions).

As published in NIH’s FY 2016 congressional justification for budget:

“Through this initiative, NIH and its partners are driving the development and use of innovative technologies to produce a clearer, dynamic picture of the brain that can show, for the first time, how individual cells and complex neural circuits interact in both time and space. This multi-agency initiative leverages the unique strengths of NIH, the Defense Advanced Research Projects Agency (DARPA), the National Science Foundation (NSF), the Food and Drug Administration (FDA), and the Intelligence Advanced Research Projects Activity (IARPA), as well as private funders. Given the ambitious goals of the BRAIN Initiative, success will require ideas from the best scientists and engineers across many diverse disciplines. NIH’s funding priorities have been guided by a high-level working group of the Advisory Committee to the NIH - the NIH BRAIN working group - which was composed of expert scientists around the country. Its planning process sought input broadly from the scientific community, patient advocates, and the general public.” (“Obama Administration Proposes Over $300 Million in Funding for the BRAIN Initiative.” 2016).
Programs at NIH continue to develop new treatments and tools to assist with the BRAIN initiative goals:

“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.” (“Obama Administration Proposes Over $300 Million in Funding for the BRAIN Initiative.” 2016)

DARPA was appropriated $2.87 billion in funding by Congress for FY 2016, while the President requested $2.97 billion. Per GPRA mandated DARPA budget report, $2.868 billion was the actual spent amount in FY2016. Out of which, $95 million was dedicated to just BRAIN initiative-specified research.

Figure 12. Fiscal year 2016, actual funding utilized vs. the BRAIN initiative-specific budget for DARPA (in billions).

As published by the White House BRAIN initiative propositions:

“In FY 2016, DARPA plans to invest an estimated $95 million to support The BRAIN Initiative. DARPA’s investments aim to leverage brain function 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.” (“Obama Administration Proposes Over $300 Million in Funding for the BRAIN Initiative.” 2016)

Programs at DARPA continue to accelerate and take the BRAIN initiative goals to another level with:

“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.” (“Obama Administration Proposes Over $300 Million in Funding for the BRAIN Initiative.” 2016).

Table 21. Summary of NIH and DARPA President’s budget requests, Congressional appropriations, and BRAIN initiative budget allocations by the respective Agency.

<table>
<thead>
<tr>
<th>NIH R&amp;D Funding FY</th>
<th>President’s Budget Request</th>
<th>Congress Budget Appropriations</th>
<th>Actual Funding Utilized</th>
<th>BRAIN Initiative Budget Dedications</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>$ 31.331 billion</td>
<td>$ 30.151 billion</td>
<td>$ 29.926 billion</td>
<td>$ 40 million</td>
</tr>
<tr>
<td>2015</td>
<td>$ 30.40 billion</td>
<td>$ 30.362 billion</td>
<td>$ 30.311 billion</td>
<td>$ 100 million</td>
</tr>
<tr>
<td>2016</td>
<td>$ 32.311 billion</td>
<td>$ 31.311 billion</td>
<td>$ 31.381 billion</td>
<td>$ 135 million</td>
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<table>
<thead>
<tr>
<th>DARPA R&amp;D Funding FY</th>
<th>President’s Budget Request</th>
<th>Congress Budget Appropriations</th>
<th>Actual Funding Utilized</th>
<th>BRAIN Initiative Budget Dedications</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>$ 2.86 billion</td>
<td>$ 2.75 billion</td>
<td>$ 2.752 billion</td>
<td>$ 38 million</td>
</tr>
<tr>
<td>2015</td>
<td>$ 2.91 billion</td>
<td>$ 2.87 billion</td>
<td>$ 2.915 billion</td>
<td>$ 80 million</td>
</tr>
<tr>
<td>2016</td>
<td>$ 2.97 billion</td>
<td>$ 2.87 billion</td>
<td>$ 2.868 billion</td>
<td>$ 95 million</td>
</tr>
</tbody>
</table>
Summary of Results for Part I, II, and III:

In this chapter, data was collected using different methods and techniques in parts I, II, and III of the research study. Part I focused on data obtained via interviews with agency personnel and researchers to establish ethical and legal dimensions in public policies associated with neuro S&T research from NIH and DARPA. The data, collected through interviews with agency personnel, enabled us to generate categories of how agencies participate, allocate funding, and addressing societal views associated with neuro S&T research. The data collected through interviews with extramural researchers enabled us to establish categories and information on, ethical issues, legal issues, societal views, addressing societal views, mitigation strategies, and research use by public in their research-specific programs. The specifics of what these categories mean and the potential impact will be discussed in the next section.

Part II, secondary data from Pew Research Center, was collected to see how the general public feels about obtaining a specific type of neuro S&T research treatment. Overall, in the population, over 72% responded negatively to obtaining a “brain implant to improve your memory or mental capacity”. The data was then divided by the independent variables of religion, education, and age to see if these variables affected how individuals feel about utilizing a specific neuro S&T research treatment. In all of the independent variables, a higher percentage said no then yes when asked if they would want a “brain implant to improve your memory or mental capacity”. The specifics of these results will be analyzed in the next section.

In part III, Presidential budget recommendations, the respective congressional appropriations bills, and the GRPA mandated reporting of actual funding utilized by agencies were reviewed for the BRAIN initiative, for fiscal years 2014, 2015, and 2016 for both DARPA and NIH. The purpose was to see whether the budgets for the three years since the BRAIN
initiative started showed a pattern in how funding is obligated federally and how it impacts funding obligations within an agency. The research and development budget showed an increase for both agencies (DARPA and NIH) and also showed an increase in budget allocations for BRAIN initiative-specific research allocations at the respective agencies. The impact of why these changes in funding might have occurred will be discussed in the next section.

Analysis

In this section, we will be analyzing the collected data and establish whether the data answered the proposed questions and whether the hypotheses can be accepted or rejected. The central research question to be addressed in this study was how agencies that follow the Presidential BRAIN initiative address ethical, legal and societal views on neuro S&T research. Specifically, several subsidiary questions were to be addressed as a result of the findings:

- What types of ethical questions does the science involving translational neuroscience research raise for the public (and who raises these questions)?
- What types of legal ramifications do these ethical questions raise and how does public policy address these ramifications?

The hypotheses of this study, generated largely from the scientific, policy, legal, and opinion literature were:

- $H_1$: If an agency’s leadership is a Presidential appointee, and a Presidential Initiative falls within their mission, then the agency is pressured to focus their work to align with the initiative.
• H₂: If societal needs outweigh the ethical and legal risks associated with a particular neuroscience and technology research, then the research will be funded by an agency, contingent upon a mitigation strategy.

Analysis of Agency Participation (H₁)

Both DARPA and NIH have directors that are Presidential appointees. However, they differ in their mission, vision, and structure along with Federal alignment (which changes the policies and guidelines they have to adhere to for ethical and legal issues; DARPA/DoD and NIH/DHHS). Funding data was collected through two different mechanisms. The first was collected through interviews with agency personnel at DARPA and NIH and the second through review of archival records, specifically Presidential budget recommendations and congressional appropriations bills, as well as GPRA mandated agency reports of actual budget utilization for fiscal years 2014, 2015, and 2016. Let us first analyze the data gathered through interviews with agency personnel.

a. Choosing to Participate:

According to NIH and DARPA interviewees, participation in the BRAIN initiative for NIH was in response to the Presidential BRAIN initiative in 2013. The responses from the interviewees showed:

NIH: In response to this, NIH convened a working group of the Advisory Committee to the Director (ACD) to develop a rigorous plan for achieving the scientific vision put forth by the BRAIN initiative. This working group sought broad input from the scientific community, patient advocates, and the general public. Their report, BRAIN 2025: A Scientific Vision, released in June 2014. The report articulated the scientific goals of the BRAIN Initiative and developed a
multi-year scientific plan for achieving these goals, including timetables, milestones, and cost estimates. The BRAIN Initiative is funded through set-asides in congressional appropriation annually. This money is mandated for use on BRAIN initiative and is separate from money allocated and appropriated to individual institutes at NIH for their individual missions/goals. Therefore, participation in the BRAIN initiative was based on NIH’s mission, vision, and funding allocation by the Office of Management and Budget (OMB), and direct involvement through the working groups involved with the BRAIN initiative.

Following the announcement of the BRAIN initiative, the involvement of NIH changed as the goals set forth by the President were ambitious and bold. The working group agreed that, in its initial stages, the best way to enable these goals is to accelerate technology development. The focus is not on technology per se, but on the development and use of tools for acquiring fundamental insight about how the nervous system functions in health and disease. In addition, since this initiative is only one part of the NIH’s substantial investment in basic and translational neuroscience, these technologies are evaluated for their potential to accelerate and advance other areas of neuroscience as well. However, in 2017, when the new Presidential administration took office, no change was seen in how the BRAIN initiative was being conducted. Participation in the BRAIN initiative remained the same as the previous administration.

DARPA: DARPA was already conducting research and had several programs already involved in neuro S&T. Therefore, existing and planned programs ended up aligning with some of the goals set forth by the BRAIN initiative. The BRAIN Initiative is funded through set-asides in congressional appropriation.
appropriation annually. This money is mandated for use on the BRAIN initiative and is separate from money allocated and appropriate to other programs at DARPA for their individual missions/goals. Therefore, participation in the BRAIN initiative was based on DARPA’s mission, vision, and funding allocation by the Office of Management and Budget (OMB), and direct involvement through the working groups involved with the BRAIN initiative.

Following the announcement of the BRAIN initiative, the DARPA neuro S&T programs adopted a stronger focus on physiological mechanisms: during this same time a new office was stood up by DARPA, which focus specifically on Biological Technologies. DARPA’s focus is on technology development and use of tools for acquiring fundamental insight about how the nervous system functions. In addition, since this initiative is only one part of the DARPA’s substantial investment in basic and translational neuroscience, these technologies are evaluated for their potential to accelerate and advance other areas of neuroscience as well. However, in 2017, when the new Presidential administration took office, no change was seen in how the BRAIN initiative was being conducted. Participation in the BRAIN initiative remained the same as the previous administration.

b. Allocation of Funding:

1. Interviewee Data:

Per the interviewees, funding for the BRAIN initiative at DARPA and NIH is allocated keeping several different issues in mind. Funding is allocated/appropriated through congressional mandates annually. Their responses showed that:
NIH: Money appropriated to NIH contains set-asides for each individual institute and for the BRAIN initiative. The BRAIN Initiative funding opportunities are developed and awarded using the guidance of the BRAIN 2025 Report. NIH staff supporting the BRAIN Initiative analyze proposals and progress/success of awarded projects to determine the exact pace for progressing through the goals of BRAIN. The main factors are analysis of ongoing activities, pre-existing needs, and timing (which is how much funding is available relative to the end of the fiscal year and whether it is a single year or multi-year mandate). The relative need for the technology is especially considered and is assessed based on receipt of input from public workshops and requests for information through different channels. Therefore, overall, the scientific needs/merit, technical needs/merit, opportunities (existing and anticipated), and availability of funds, all play an integral role in figuring out how funding is allocated. In 2017, when the new Presidential administration took office, no change was seen in how the BRAIN initiative was being conducted. Funding allocations for the BRAIN initiative remained the same as the previous administration.

DARPA: Money appropriated to DARPA contains set-asides for programs and for the BRAIN initiative. The BRAIN Initiative funding opportunities are developed and awarded using the guidance of the DARPA Director, program managers, and support staff. DARPA staff supporting the BRAIN Initiative analyze proposals and progress/success of awarded projects to determine the exact pace for progressing through the goals of BRAIN.

The main factors are analysis of ongoing activities, pre-existing needs, and timing (which is how much funding is available relative to the end of the fiscal year and whether
it is a single year or multi-year mandate). The relative need for the technology is especially considered and is assessed based on receipt of input from public workshops and requests for information through different channels. In addition, funding decisions are based on potential impact. DARPA program managers always ask the question “how would the proposed technology leap ahead of the state of the art? and “if successful, what difference will it make?” Therefore, overall, the scientific needs/merit, technical needs/merit, opportunities (existing and anticipated), and availability of funds, all play an integral role in figuring out how funding is allocated. In 2017, when the new Presidential administration took office, no change was seen in how the BRAIN initiative was being conducted. Funding allocations for the BRAIN initiative remained the same as the previous administration.

2. Research and Development Funding Allocations

Evaluating the budgets for the three years since the BRAIN initiative started (FY 2014, 2015 and 2016) showed a pattern in how funding is obligated federally and how it impacts funding obligations within an agency. Review of the President’s budget recommendation, the congressional budget allocations and the GPRA mandated actual budget utilization reports, provided the fiscal scope (funding obligations by agency and federal research and development budget, towards neuro S&T research) and scale of the research and the number and distribution of research.

NIH had a continual increase in R&D funding from congressional appropriations from $30.151 billion in 2014, $30.362 billion in 2015, and $31.311 billion in 2016 (figure 7). This increase caused them to allocate more funding towards the BRAIN initiative as well, from $40 million in 2014, $100 million in 2015 and $135 million in 2016 (figure 7). The number of
programs that were funded by NIH also increased as the funding towards the BRAIN initiative increased in a given fiscal year.

Figure 13. NIH R&D funding allocations, graph shows an increase in the amount of funding over fiscal years 2014, 2015, and 2016.

DARPA is much smaller than NIH and therefore there is a big difference in their budgets (as discussed in chapter 2). However, DARPA’s budget also saw an increase from fiscal years 2014 to 2015 (from $2.75 billion to $2.87 billion) but stayed the same between 2015 to 2016 ($2.87 billion) (figure 8). Even though their funding did not increase between 2015 to 2016, their allocations towards BRAIN initiative increased, from $38 million in 2014, $80 million in 2015, and $95 million in 2016 (figure 8). The number of programs that were funded by DARPA also increased as the funding towards the BRAIN initiative increased in a given fiscal year.
Figure 14. DARPA R&D funding allocations, graph shows an increase in the amount of funding over fiscal years 2014, 2015 but shows no change from 2015 to 2016.

In comparing the budget allocations towards the BRAIN initiative by DARPA and NIH, we do not see a big difference, despite a big difference in their overall budget by Congress. This might be due to several reasons. As discussed in chapter 2, the organizational and structural differences between the two agencies are vast. DARPA has approximately 240 employees, whereas NIH has over 2000 employees. However, the research portfolio for neuro S&T research is comparable for both institutes. Since DARPA’s research projects have a short turnaround and are run on a short timeline (mostly 1-3 years), NIH-funded researchers have a longer time frame to complete a research project and their projects tend to run longer (2-4+ years). Therefore, DARPA’s BRAIN initiative-funded portfolio increased over the years significantly, especially when compared to their overall budget for the agency, as they were funding a lot more projects. NIH, on the other hand, compared to their overall funding for R&D and their BRAIN initiative
funding, an increase is seen, but not as significant as that of DARPA’s neuro S&T portfolio. This might be due to their less restrictive turnaround times for research projects (see figure 15 below).

Figure 15. DARPA’s and NIH’s BRAIN initiative focused funding for fiscal years 2014, 2015, and 2016.

Therefore, through analysis of the data, we can state that our first hypothesis can be rejected, that

H1: If an agency’s leadership is a Presidential appointee, and a Presidential Initiative falls within their mission, then the agency is pressured to focus their work to align with the initiative.

At the beginning of this study, we chose to explore how DARPA and NIH, two agencies that are so vastly different in their mission, vision, and structure along with Federal alignment (which changes the policies and guidelines they have to adhere to for ethical and legal issues; DARPA/DoD and NIH/DHHS), choose to participate in the BRAIN initiative. Through analysis of the data, we saw that choosing to participate in the BRAIN initiative aligned with DARPA’s and NIH’s structure, mission, and vision. NIH answered the call for participation in the BRAIN
initiative by increasing the development and use of tools for acquiring fundamental insight about how the nervous system functions in health and disease. DARPA was already working on neuro S&T research, specifically funding neuro S&T research projects that focused on making technological advances for treatments of diseases associated with the brain. However, DARPA increased their neuro S&T portfolio and answered the President’s call in taking the BRAIN initiative forward. Data that was collected via interviews with agency personnel and researchers for both agencies gave similar responses to choosing to participate and allocating funding. While we believed the responses should be very different due to the two agencies being completely different from each other, it seems, in following the BRAIN initiative funding for extramural research, specifically neuro S&T research that can be translated into public use, DARPA and NIH follow a very similar path.

However, we must also keep in mind that both agencies are federally funded and have Presidential appointees as Directors. Therefore, when the Presidential administration changed in 2017, both agencies should have been impacted in how they were participating and funding the BRAIN initiative. But based on their responses, for now (with the new administration being in the office for 9 months), no changes have been seen. In June 2017, President Trump, decided to retain the current NIH Director, Dr. Francis Collin to continue serving NIH during his presidency. However, DARPA is currently functioning with an acting Director, as the new administration has not appointed a new Director to this agency. In the future, we might be able to see changes but to date no changes have been seen, therefore the first hypothesis for this study cannot be accepted.

Ethical, and Legal risks vs. Societal Needs (H2)
Data collected from DARPA and NIH agency personnel and researchers, provided insight into how ethical and legal risks that are being posed by the selected programs are assessed, addressed and mitigated prior to any funding being issued. Per the interviewees:

a. Ethical issues
NIH: are being addressed through utilizing internal and external ethical oversight. A specific Neuroethics Working Group (NWG) has been formed that is charged with helping anticipate and address new and unique ethical issues that the BRAIN research will generate.

DARPA: are being addressed through utilizing internal and external ethical oversight. An ELSI panel of external experts across each of the disciplines (ethics, legal, societal) provides insights and feedback on the Agency’s neuroscience programs.

b. Legal issues
NIH: are being addressed through internal legal oversight of the general council. In addition, the NWG is co-chaired by a professor of law who specializes in neurolaw and neuroethics.

DARPA: are being addressed through internal legal oversight of the general council. In addition, the ELSI panel has experts that specialize in neurolaw and neuroethics.

c. Societal needs
NIH: are being assessed through external and internal oversight to ensure unbiased enrollment/distribution does not occur. Every proposal is required to explicitly address what their plans are for ensuring appropriate representation for participants in their study and to specifically show the need for the research effort. Typically, these proposals are
reviewed by committees at the researcher’s organization, scientific review panel, and the NIH staff prior to being awarded funding.

DARPA: are being assessed through external and internal oversight to ensure unbiased enrollment/distribution does not occur. Every proposal is required to explicitly address what their plans are for ensuring appropriate representation for participants in their study.

In addition, a detailed description is required on why this technology is needed, a lot of emphasis is given to this when deciding to allot funding for a new or ongoing effort.

Typically, these proposals are reviewed by committees at the researcher’s organization, ELSI panel, and the DARPA staff prior to being awarded funding. DARPA programs work at a very quick pace. The goal is to have technologies transition quickly into commercial production for public distribution and use.

As shown in table 22 below, a side-by-side comparison of DARPA and NIH shows how both agencies address the societal views of ethical and legal issues with research programs that they fund through their agencies. Both agencies utilize internal and external mechanisms to control for potential risks associated with the funded research. The external boards, such as the ELSI panel used by DARPA and the NWG panel used by NIH, have members that are experts in all fields of neuroscience, as well as outside experts that provide a worldview of society and the impacts of these technologies. Therefore, it can be safely assumed that work on these technologies goes through rigorous steps prior to even research beginning, to ensure these technologies are for benefit and not induce more harm than good.
Table 22. Side-by-side comparison of how DARPA and NIH, as agencies, address the potential barriers that surround neuro S&T research.

<table>
<thead>
<tr>
<th>DARPA Addressing Societal Views</th>
<th>NIH Addressing Societal Views</th>
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<tbody>
<tr>
<td>Opportunity Costs</td>
<td>Opportunity Costs</td>
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<tr>
<td>Cost-benefit Analysis</td>
<td>Cost-benefit Analysis</td>
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<td>Ethical</td>
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<tr>
<td>• External Institutional Review Boards</td>
<td>• External Institutional Review Boards</td>
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<tr>
<td>• Implementing Internal Ethical Oversight</td>
<td>• Implementing Internal Ethical Oversight</td>
</tr>
<tr>
<td>• Ethical, Legal, and Societal Panel</td>
<td>• Neuroethics Working Group</td>
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<tr>
<td>Legal</td>
<td>Legal</td>
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<tr>
<td>• Internal Legal Oversight (general council)</td>
<td>• Internal Legal Oversight (general council)</td>
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<td>• Ethical, Legal, and Societal Panel</td>
<td>• Neuroethics Working Group</td>
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<tr>
<td>Societal Need</td>
<td>Societal Need</td>
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<td>• External Oversight to Ensure Unbiased Enrollment/Distribution</td>
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<td>• Ethical, Legal, and Societal Panel</td>
<td>• Neuroethics Working Group</td>
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<tr>
<td>• Quick transition to facilitate commercial production for public distribution and use</td>
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d. Mitigation Strategies:

The researchers interviewed, either personally or through their organizations, had mitigation strategies to address the ethical, legal, and societal views of the public. They want to work to address them prior to public release of their technology/treatment to ensure that the general public is accepting of the research. From inception of an idea to execution, researchers are thinking about how to proceed forward depending on who the stakeholders are and who the end
users will be. Those decisions are made and thought about very actively during the very initial stages.

NIH: Most researchers have essentially an open-door policy to any oversight. They could have a site visit from the FDA, Joint Interface Control Office (JICO), funding organization, reviewing IRB, or Institutional Animal Care and Use Committee (IACUC). Anyone of these large stakeholders could come into the lab at any time for review of records or research documents and the researchers make them available.

Another mitigation strategy is a rigorous consent process. In some cases, consent process is months-long in terms of initial discussions and descriptions of the study and conversations about how the study rolls out, what the surgical components are, etc. Researchers are also cautioned to speak to media about research that has not been peer reviewed. Sharing of information prior to it being at least vetted externally amongst another group of experts can quite often be counter-productive because what's being shared either is not true or can be considerably over-represented in the press, and that is where, as field, neuro S&T can get into trouble. In addition, researchers suggest as a rule to only speak about what they are trained to talk about. If a question delves into something that is not their specialty, then just refer the interviewer to someone who can best answer. The worst thing you can do is state something that is inaccurate or that has not been peer reviewed. Avoid hyperbole at all costs.

DARPA: Education is key to avoiding backlash, fear, and conspiracy theories in the general public. Overpromising is counterproductive; results should be stated as is and not stated with what could potentially be reached one day. Voluntary adoption of technology is critical. The deaf community was initially resistant to cochlear implants. Any law requiring parents to restore hearing to their deaf children would have been a mistake. Medical choices should be made by
patients (and their caregivers) in consultation with their physician(s). These issues need informed discussion that includes the scientists, engineers, and technologists developing the systems, regulatory bodies who help manage and regulate deployment at a systems level, physicians and therapists who would be responsible for providing these technologies directly to users, end users of the technologies, and importantly, insurers who would need to make decisions about supporting these technologies. Careful thoughtfulness and making clear efforts to ensure that the technologies are mindfully developed will go a long way towards addressing and mitigating many of the key barriers to effectively helping the end users.

Therefore, if the general public is made aware of all the steps researchers and agencies have taken and are taken to ensure ethical and legal oversight of federally funded neuro S&T research, that will certainly change their outlook and the use of these technologies.

Thus, analysis of this data allows us to accept our hypothesis that:

$H_2$: If societal needs outweigh the ethical and legal risks associated with a particular neuroscience and technology research, then the research will be funded by an agency, contingent upon a mitigation strategy.

Through analysis of the interviews by the agency personnel and researchers, we were able to see how agencies and researchers find and resolve ethical, and legal issues surrounding neuro S&T research. Each proposal that is reviewed for funding, must provide a detailed plan on why this neuro S&T is needed for society. If the need outweighs the ethical and legal risks associated with the research, then the research is funded contingent upon a detailed mitigation plan for all risks associated with the study. While we believed the responses should be very different due to the two agencies being completely different from each other, it seems in following the BRAIN initiative funding for extramural research, specifically neuro S&T research that can be translated.
into public use, DARPA and NIH follow a very similar path. The level of ethical and legal oversight in finding and resolving these potential issues is high and thus can be an assurance to the general public, as the researchers and agency personnel are working diligently to conduct work of the highest ethical and legal standards at both DARPA and NIH.

Central Research question

The central research question to be addressed in this study was how agencies that follow the Presidential BRAIN initiative address ethical, legal and societal views on neuro S&T research. The data collected through part I, II, and III of this study (interviews with DARPA and NIH extramural-funded researchers) helped us in addressing these questions. In interviews with the researchers about their specific programs, HAPTIX and ElectRx (DARPA) and Next Generation Human Imaging and Next Generation Human Invasive Devices (NIH), both programs that result in producing translational neuroscience technologies, the ethical and legal ramifications of these programs became evident.

a. Researchers Addressing Ethical, Legal and Societal Views:

Researchers involved in this work are very cautious about ensuring that all ethical, legal and societal views that are foreseen are addressed and resolved as soon as possible. Research with human subjects is heavily regulated. Researchers want to ensure they conduct work with the highest ethical standards and eliminate as much harm as possible in their respective studies.

NIH: All of the research that was funded by NIH to support the BRAIN initiative goes through rigorous review and oversight. The funded researchers have to obtain approvals from their local IRBs and NIH IRB, as well as work with their Neuroethics Working Group (NWG). Most issues regarding potential barriers are first addressed by the researcher and his team internally through review and collaboration. Outside guidance is
sought where needed. Data safety monitoring boards and Food and Drug Administration (FDA) oversight and approvals are obtained for device use, etc.

DARPA: Research is reviewed by multiple regulatory bodies, including the FDA, local IRB, and potentially outside IRBs such as the Department of Defense IRBs, that review every aspect of studies from recruitment methods and screening language through to study procedures and follow-up care. This provides the most rigorous way to assess proposed research studies. Typically, interaction between the regulators and researchers occurs and is a way to resolve differences to arrive at a final study protocol. These protocols are occasionally audited. It is however up to the researchers to comply with the agreed upon protocol and to report deviations or adverse events.

Researchers believe that the study investigator must be sure that any proposed risk is accompanied by sufficient benefit (to the subject or in terms of research data acquired) to justify the study. This internal barrier is critical in the ethical considerations of the researcher. Working in a multi-investigator environment can provide an opportunity to discuss these risk-benefit ratios that are ultimately the determinant of whether a particular research study is proposed to an external regulator.

Both DARPA and NIH extramural-funded researchers have established mechanisms that point to how to address the potential barriers surrounding their research that affect the research and technology’s distribution and use. These issues are addressed prior to and during the research being conducted. There are several different levels of oversight and internal and external review of all aspects of the research study. These mechanisms ensure all research is conducted with the highest ethical standards and minimizes all risks associated with the research.
Research is conducted with high ethical standards, while keeping all the legal and societal issues in mind throughout all phases of the research study.

b. Public Use

Fiscal year 2014 was the first year that DARPA and NIH received BRAIN initiative-specific funding. In the same year (2014), Pew Research Center conducted a survey of 1,001 adults. The individuals were asked “would you personally do this-get a brain implant to improve your memory or mental capacity?” Of the 3267 individuals surveyed, approximately 49% were male and 51% were female. Of the males in the population, the highest number of individuals were white, between the ages of 18-29, and with an education of high school or less. Of the females in the population, the highest number of individuals were black, over 65 of age, and with some college education completed. However, we must note that in analyzing the demographics, the percentages did not vary too far with +/- difference of 5% within the different criterions assessed. Therefore, it is safe to assume that the data is based on survey of a complete population across the U.S. of males and females, from all ethnicities, ranging from 18-65+ in age, and education from less than high school to college graduate or more. Out of the 3,267 individuals surveyed, 848 individuals said yes, 2,357 said no, and 62 answered don’t know or refused to answer this question. Therefore, in this population, individuals would rather not get a brain implant (72.1%), even if it means that they would have a better memory or mental capacity resulting from the procedure.

In order to see if an individual’s religion, education, or age affected their response, cross-tabulation analysis was run against these variables.

- Religion:
The cross-tabulation analysis, was run only on those individuals that either answered yes or no; the individuals that answered don’t know or refused to answer were marked as unknown in the analysis test. Within the population, the highest percentage of individuals surveyed were Christians and the lowest number of individuals were Hindus. In assessing the responses, those individuals that identified themselves as having a religious preference answered no to obtaining a brain implant, wherein 74.7% of Christians, 66% of Jewish, 86.2% of Muslim, 66.7% of Buddhist and 50% of Hindu answered no. However, out of all the categories, the highest number of individuals to say yes to obtaining a brain implant within a group were those that have identified themselves as having a Hindu religious affiliation. Therefore, we can state that religious affiliation does influence an individual’s views on brain research.

- Education:

The cross-tabulation analysis was run only on those individuals that either answered yes or no; the individuals that answered don’t know or refused to answer were marked as unknown in the analysis test. Within the population, the highest percentage of individuals surveyed were those that had completed high school and the lowest number of individuals were those that had completed less than high school. In assessing the responses, within the groups, those individuals that had completed less than high school 64% said no; in the category for high school, 78% said no; college, 80.7% said no; bachelor’s degree, 63.5% said no, and those that had completed postgraduate or above, 60.2% said no. Therefore, in all categories, a higher percentage said no compared to those that said yes. However, out of all the categories, the highest number of individuals to say yes to obtaining a brain implant
within a group were those that have completed postgraduate education or above. Thus, education does influence an individual’s views on brain research.

- Age:

The cross-tabulation analysis was run only on those individuals that either answered yes or no; the individuals that answered don’t know or refused to answer were marked as unknown in the analysis test. Within the population, the highest percentage of individuals surveyed were those in the age group of 30-49 and the lowest number of individuals were those that were in the age group of 65 and over. In assessing the responses, within the groups, those individuals that were in the age group 18-29 77.4% said no; in the age group of 30-49, 76% said no; aged 50-64, 69.3% said no; and aged 65 or over, 71.2% said no to obtain a brain implant to improve their mental capacity or memory. Therefore, in all categories, a higher percentage said no compared to those that said yes. However, out of all the categories, the highest number of individuals to say yes to obtaining a brain implant within a group were those that were in the group of 50-64 years of age. Thus, we can state that age does influence an individual’s views on brain research, where the older you get, the higher your acceptance is of neuro S&T research. It would be interesting to see, if this same survey was conducted in 2017, whether the responses of the individuals would have changed.

In asking the researchers in their opinion on whether they think neuro S&T will face resistance by the general public, their answers all veered in the same direction, “it depends”.

NIH: Researchers recommend that there has to be open dialogue between the patients or their representatives, the end users (people who will potentially benefit from these developments), the people who are developing them, and the intermediaries (who,
in the case of medical devices are surgeons who would be implanting them). If this is done then the structure does impose much higher barriers to adoption than, less invasive therapies or less invasive options would. This dialogue and discussion will cause the researchers to have a built-in barrier, within their research, which will prove vitally important to mitigation and acceptance of these technologies/treatments. We have to elevate the scientific literacy and improve people's ability to make judgements about what should be done and what should be funded. If researchers ensure that their work is well-vetted and peer reviewed prior to releasing the results, the acceptance will be highly likely and will face less apprehension.

DARPA: Researchers believe that the majority of the public will generally embrace technology as it relates to neuroscience. This is even true of invasive, implantable systems. In many areas, the general public are very quick to embrace new technologies, and researchers see no reason that this will not extend to neuroscience and prosthetics. Any apparent resistance to advanced prosthetics to date likely has far more to do with their generally poor functionality as opposed to a resistance to the idea of the technology itself. This is true for neural prosthetics as they are used for treating disease and injury. However, researchers do anticipate significant backlash to neuroprosthetics for augmentation, and this is an area where the research community should tread carefully.

Acceptance of new treatments for serious psychiatric conditions will depend on public awareness that psychiatric conditions are medical conditions and reflect real problems in the brain. It is not clear how the public will view new technologies to improve learning. People like the idea of saving time, but they expect that there will be
no “free lunch” and will worry about side effects and unintended societal consequences. The public perception will likely mirror that of other performance enhancing products. Better nutrition and training is embraced, while doping and steroids are shunned. Most researchers believe that there is certain to be some vocal resistance to any new technologies, but as long as the medical community is on board, acceptance will widespread overtime.

One theme which keeps on emerging over and over through the interviews, literature review, and collected data is ensuring proper involvement of the stakeholders. The stakeholders have to be involved in key discussions and be part of the open communication process to ensure a safe and secure way in moving forward with these technologies. There are many stakeholders involved in the BRAIN initiative. From the public to the President, everyone is involved either directly or indirectly in the initiative. However, the main stakeholders involved are the Federal government agencies conducting the research with the funding and the general public:

- The Federal Government is a very important stakeholder involved in this initiative. The Federal government is allocating the funding through the research and development budget for the initiative. In addition, in the research and development budgeting, it is also listed which areas the agencies who want to receive the funding should focus their research on. Therefore, they are the main drivers behind the initiative and the outcomes they want to see through the initiative.

- Agencies receiving the funding from the government are also important stakeholders in this initiative. From utilizing the BRAIN initiative funding, to ensuring proper measures are in place for ethical, legal, and societal addressing of potential barriers that can be faced by these technologies, their work begins from the inception of an idea and
continues until the public accepts the work they funded by using it and benefiting from it, resulting in an overall societal benefit.

- The general public is also a very important stakeholder in this initiative. Their involvement is twofold: first, in how the tax payers’ money is being distributed and second, they are on the receiving end of the products/treatments being developed through this initiative. Despite the public apprehension and refusal to utilize the new neuro S&T research, they will still be pushed in that direction through their healthcare providers once the treatments become mainstream. Therefore, their involvement in this initiative is major in every way.

- The individual directly affected by the initiative. A very important stakeholder, which should be and is present front and center in this research are the individuals that are directly affected by the research being conducted through this initiative. These are the individuals that are either participating in the research themselves, or will directly utilize the technologies being researched. They are in immediate need either personally or through association of a family member or friend. Therefore involvement is by far the most important as their views (ethical and legal) on these technologies will be the most relevant.

We can see that both agency personnel and researchers are utilizing both internal and external aid to figure out and address all possible issues relating to neuro S&T. Public outreach programs including open call meetings and webinars are being held by neuro S&T societies. These outreach programs through agencies have potential to influence the outlook of the public and decrease their apprehension on the use of these technologies. The key is communication between the stakeholders. Thus, the fact that DARPA’s programs focus on treatments through
technology and NIH’s programs focus on health and disease treatments becomes just the path they are taking to focus their research on different aspects of the BRAIN initiative, but the guidelines, policies, and steps that they are taking to fund, participate, and address ethical, legal, and societal view of the public surrounding their programs are very similar. The extent of the oversight is multifaceted, with internal/external ethical and legal boards, open public meetings, involvement of all stakeholders, open door policies, internal/external education and data calls. This level of attention to issues will ensure that the transition of these technologies when released for use by the general public will go efficiently and result in being beneficial to the masses.

**Addressing Subsidiary Questions**

Specifically, several subsidiary questions were to be addressed as a result of the findings:

Question no. 1: What types of ethical questions does the science involving translational neuroscience research raise for the public (and who raises these questions)?

- **Ethical Issues**

  Per the interviewees, the ethical issues that surround the programs selected from the NIH- and DARPA-funded BRAIN initiative are diverse and complex in nature.

  NIH: For example, with issues related to subjects with disorders of consciousness, ethical issues of civil rights and disability rights take center stage. These two fall broadly under the justice argument. The issue of autonomy also comes up especially in brain-computer interface concepts, where we are taking people who require, assistance with everything and potentially granting them the ability to, now, do some things for themselves that they otherwise could not. The goal of the research is, in many ways, to restore autonomy that has been produced as a result of neurologic disease or injury. It is more along the lines of
improving or returning more towards normal, while not veering into augmentation.

However, other programs do veer into the issue of augmentation. Therefore, the issues of autonomy, freedom, fairness, and augmentation are some of the most common ethical issues surrounding these research endeavors.

**DARPA:** As the experiments become more complex and invasive, the level of expectation that the risk vs benefit ratio must rise. Essentially, the researcher must internally justify the risk-benefit ratio for an experiment. The primary ethical challenge will focus on augmentation of human performance. Currently, research is geared towards rehabilitation purposes, which leads to issues of autonomy, freedom, and fairness. However, as these technologies progress, there is the real possibility that we will eventually develop prosthetic systems that are capable of enhancing normal human performance. Especially, when technology becomes mainstream and those that wish to “enhance” and can afford to can potentially affect the rich/poor divide.

In addition, for issues related to subjects with disorders of consciousness, ethical issues of civil rights and disability rights take center stage. The issue of autonomy also comes up especially in brain-computer interface concepts, where we are taking people who require, assistance with everything and potentially granting them the ability to, now, do some things for themselves that they otherwise could not. Therefore, the issues of autonomy, freedom, fairness, and augmentation are some of the most common ethical issues surrounding these research endeavors.

As discussed above and shown in table 22, the ethical questions that these programs raise are diverse and complex in nature. The researchers and their external and internal reviewers raise these issues themselves, as they know the research much
better than anyone else and the ramifications it can have. Issues of autonomy, fairness, augmentation, increasing the rich/poor divide, etc. are just some that were raised by the researchers themselves.

Question no. 2: What types of legal ramifications do these ethical questions raise and how does public policy address these ramifications?

- Legal Issues

Based on the respondents, legal issues surrounding the NIH and DARPA-funded BRAIN initiative programs stem from laws that are already governing us. These laws, when looked at in the light of the technologies and treatments being provided by the neuro S&T research, give rise to issues of justice and fairness. In terms of the issues of justice and fairness, it seems appropriate that research participants deserve to be looked after from a medical perspective for health care and associated costs that result from their implanted devices. In counties with socialized or single-payer health care, this could be less problematic, but in the United States, this is an issue.

NIH: In addition, legal issues could rise from side effects that are not anticipated through use of a particular device or treatment. It gets to the fundamental questions of “who”? Who is actually in control, and who is actually driving? The prosthetics are a good place to start, but that is not where these issues rise. That is only because it meets a need and that it is a pathway in, as perceptual integration starts to take hold. For the question of “who”, how do you physically define “who”? Questions of ownership and legality, and questions of ethics, intent, agency, and engagement then become very nebulous. Who actually is the who? Is it the system? Is it the system’s input? Is it the person who built the system that integrates with the person, even though the person
believes that from a systems perspective, that they are a part of this larger system? So it really gets down to the question of who. This makes it difficult to decide the culpability or responsibility of the individual. In summary, the legal issues surrounding these programs are diverse in nature, depending on the nature of the treatment/technology, but are all in the realm of justice and fairness.

DARPA: In addition, legal issues could rise from side effects that are not anticipated through use of a particular device or treatment. It gets to the fundamental questions of “who”? Who is actually in control, and who is actually driving? The prosthetics are a good place to start, but that is not where these issues rise. That is only because it meets a need and that it is a pathway in, as perceptual integration starts to take hold. For the question of “who”, how do you actually physically define who? Questions of ownership and legality, and questions of ethics, intent, agency, and engagement then become very nebulous. In summary, the legal issues surrounding these programs are diverse in nature depending on the nature of the treatment/technology, but are all in the realm of justice and fairness.

As discussed above, the legal questions that these programs raise are diverse and complex in nature. The researchers and their external and internal reviewers raise these issues themselves, as they know the research much better than anyone else and the ramifications it can have. Issues of justice, fairness, who’s in control?, unintentional legal consequences, etc. are just some that were raised by the researchers themselves.

The tables below 23 and 24, provide an overall summary of how DARPA and NIH address ethical, legal and societal views for their specific programs and its use by the public:

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<thead>
<tr>
<th>Ethical Issues</th>
<th>Legal Issues</th>
<th>Societal Needs/Views</th>
<th>Addressing Societal Views</th>
<th>Mitigation Strategies</th>
<th>Research Use by the Public</th>
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<tr>
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<td>Fairness</td>
<td>Equal distribution</td>
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<td>Transparency in research</td>
<td>Depends on treatment</td>
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<td>Justice</td>
<td>Fair distribution</td>
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<td>Involve stakeholders from beginning to end</td>
<td>Depends on how it is introduced</td>
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<td>Augmentation</td>
<td>Who is in control?</td>
<td>Insurance coverage</td>
<td>IRB (internal or external)</td>
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<td>Perception vs reality</td>
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<td>Civil rights</td>
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<td>Disability rights</td>
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<td>Individual vs. authorized enrollment</td>
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<td>Neuroethics Working Groups</td>
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<td>Individual vs. authorized enrollment</td>
<td>High technology cost</td>
<td>ELSI Panel</td>
<td>Training</td>
<td>Abuse of technology</td>
</tr>
</tbody>
</table>

Compare and Contrast Demographics

In the interviews that were conducted with the DARPA and NIH agency personnel and the extramural funded researchers, their basic demographic information was collected to see if there is any correlation in age or education when compared to the responses and demographic information collected via secondary data by Pew Research Center.

Table 25. Demographic Information for DARPA and NIH Agency Personnel and Extramural Funded Researchers.

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age</th>
<th>Education</th>
<th>Ethnicity/Race</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M/F</td>
<td>30-49</td>
<td>50-64</td>
</tr>
<tr>
<td>Male</td>
<td>21</td>
<td>14</td>
<td>5</td>
</tr>
<tr>
<td>Female</td>
<td>3</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>24</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

131
Table 25 shows that there were 24 individuals interviewed as part of this study. All of these individuals had a Ph.D. or M.D. and were white (ethnicity). As discussed previously, in our cross-tabular analysis of the secondary data collected by Pew Research Center, out of all the categories, the highest number of individuals to say yes to obtaining a brain implant within a group were those that have completed postgraduate education or above. Thus, we concluded that education does influence an individual’s views on brain research. That is the only generalizable conclusion we can draw from these two data demographics. All other variables were very different and thus cannot be compared or generalized across the board.

**Summary of Analysis:**

In summary, through analysis of the data in this chapter, we were able to answer the central research question of this study, of how agencies that follow the Presidential BRAIN initiative address ethical, legal and societal views on neuro S&T research. Table 23 and table 24, show how DARPA and NIH both agencies and researchers funded by these agencies address the potential ethical, legal, and societal views with research programs that they fund. Both agencies utilize internal and external mechanisms to control for potential risks associated with the funded research. The external boards, such as the ELSI panel used by DARPA and the NWG panel used by NIH, have members that are experts in all fields of neuroscience, as well as outside experts that provide a worldview of society and the impacts of these technologies. There are several different levels of oversight and internal and external review of all aspects of the research study. These mechanisms ensure all research is conducted with the highest ethical standards and minimizes all risks associated with the research. Researchers and agency personnel then incorporate the recommendations from these experts in their programs to ensure safe distribution and use by the public upon release of these technologies.
The interrelated questions as posed by this study that were to be addressed through the study finding were also addressed:

- What types of ethical questions does the science involving translational neuroscience research raise for the public (and who raises these questions)?

  Table 24 lists the ethical questions that these programs raise, which were found to be diverse and complex in nature. The researchers and their external and internal reviewers raise these issues themselves, as they know the research much better than anyone else and the ramifications it can have. Issues of autonomy, fairness, augmentation, increasing the rich/poor divide, etc. are just some that were raised by the researchers themselves.

- What types of legal ramifications do these ethical questions raise and how does public policy address these ramifications?

  Table 24 lists the legal questions that these programs raise, which were found to be diverse and complex in nature. The researchers and their external and internal reviewers raise these issues themselves, as they know the research much better than anyone else and the ramifications it can have. Issues of justice, fairness, who is in control?, unintentional legal consequences, etc. are just some that were raised due to these programs, by the researchers themselves.

  The hypotheses set forth through literature and data review were all validated as well through the research findings.
Rejected $H_1$: If an agency’s leadership is a Presidential appointee, and a Presidential Initiative falls within their mission, then the agency is pressured to focus their work to align with the initiative.

Through analysis of the data, we saw that choosing to participate in the BRAIN initiative aligned with DARPA’s and NIH’s structure, mission, and vision. NIH answered the call for participation in the BRAIN initiative by increasing the development and use of tools for acquiring fundamental insight about how the nervous system functions in health and disease. DARPA was already working on neuro S&T research, specifically funding neuro S&T research projects that focused on making technological advances for treatments of diseases associated with the brain. DARPA increased their neuro S&T portfolio and answered the President’s call in taking the BRAIN initiative forward. Data that was collected via interviews with agency personnel and researchers for both agencies gave similar responses to the topics of choosing to participate and allocating funding. However, as anticipated a change in how agencies were participating and allocating funding towards the BRAIN initiative programs should have been seen due to the change in the Presidential administration. But no change in how agencies are conducted neuro S&T research has been detected or reported to date, therefore, due to the data collected to date, $H_1$ has to be rejected.

Accepted $H_2$: If societal needs outweigh the ethical and legal risks associated with a particular neuroscience and technology research, then the research will be funded by an agency, contingent upon a mitigation strategy.

Through analysis of the interviews by the agency personnel and researchers, we were able to see how they find and resolve ethical and legal issues surrounding neuro S&T research, for a particular neuro S&T that is needed for a societal use. They use internal and external
subject matter experts, cost-benefit analysis, risk-reducing strategies, oversight of data safety monitoring boards, and IRBs to ensure work occurs with the highest ethical standards. While we believed the responses should be very different due to the two agencies being completely different from each other, it seems in following the BRAIN initiative funding for extramural research, specifically neuro S&T research that can be translated into public use, DARPA and NIH follow a very similar path. The level of ethical and legal oversight in finding and resolving these potential issues is high and thus can be an assurance to the general public, as the researchers and agency personnel are working diligently to conduct work of the highest ethical and legal standards at both DARPA and NIH.

In the next chapter, we will end with concluding remarks and recommendations for moving forward. These can be utilized by agencies and researchers in moving forward while drafting public policies for neuro S&T research’s distribution and use.
CHAPTER 5

CONCLUSION

In this study, I examined what the societal views are for neuroscience and technology research (neuro S&T) and the specific policy, administrative, and scientific strategies the neuroscience community is pursuing to address those views. Thus, the aim was to address the ethical and legal questions surrounding neuro S&T research by interviewing agency leaders and the scientific community, reviewing data from public surveys, and analyzing research and development funding allocations (specific to the BRAIN initiative), in order to better understand the influence of Presidential initiatives on agencies, the resulting product, and the effect it has on the general public. We chose DARPA and NIH, two agencies that have Presidential appointees but are so vastly different in their mission, vision, and structure, along with Federal alignment (which changes the policies and guidelines they have to adhere to for ethical and legal issues; DARPA/DoD and NIH/DHHS), to assess how they follow the same initiative.

Through the three-tier data collection method, the results obtained and analyzed allowed us to accept the hypotheses set forth in this study and answer the central research question. We were able to conclude that both agencies DARPA and NIH utilize internal and external mechanisms to control for potential risks associated with the funded research. The external boards, such as the ELSI panel used by DARPA and the NWG panel used by NIH, have members that are experts in all fields of neuroscience, as well as outside experts that provide a worldview of society and the impacts of these technologies. There are several different levels of oversight and internal and external review of all aspects of the research study. These mechanisms ensure all research is conducted with the highest ethical standards and minimizes all risks associated with the research. Researchers and agency personnel then incorporate the
recommendations from these experts in their programs to ensure safe distribution and use by the public upon release of these technologies.

H1: If an agency’s leadership is a Presidential appointee, and a Presidential Initiative falls within their mission, then the agency is pressured to focus their work to align with the initiative.

At the beginning of this study, we chose to explore how DARPA and NIH, two agencies that are so vastly different in their mission, vision, and structure along with Federal alignment (which changes the policies and guidelines they have to adhere to for ethical and legal issues; DARPA/DoD and NIH/DHHS), choose to participate in the BRAIN initiative. Through analysis of the data, we saw that choosing to participate in the BRAIN initiative aligned with DARPA’s and NIH’s structure, mission, and vision. NIH answered the call for participation in the BRAIN initiative by increasing the development and use of tools for acquiring fundamental insight about how the nervous system functions in health and disease. DARPA was already working on neuro S&T research, specifically funding neuro S&T research projects that focused on making technological advances for treatments of diseases associated with the brain. However, DARPA increased their neuro S&T portfolio and answered the President’s call in taking the BRAIN initiative forward. Data that was collected via interviews with agency personnel and researchers for both agencies gave similar responses to choosing to participate and allocating funding. While we believed the responses should be very different due to the two agencies being completely different from each other, it seems, in following the BRAIN initiative funding for extramural research, specifically neuro S&T research that can be translated into public use, DARPA and NIH follow a very similar path.

However, we must also keep in mind that both agencies are federally funded and have Presidential appointees as Directors. Therefore, when the Presidential administration changed in
2017, both agencies should have been impacted in how they were participating and funding the BRAIN initiative. But based on their responses, for now (with the new administration being in the office for 9 months), no changes have been seen. In June 2017, President Trump, decided to retain the current NIH Director, Dr. Francis Collin to continue serving NIH during his presidency. However, DARPA is currently functioning with an acting Director, as the new administration has not appointed a new Director to this agency. In the future, we might be able to see changes but to date no changes have been seen, therefore the first hypothesis for this study cannot be accepted.

H$_2$: If societal needs outweigh the ethical and legal risks associated with a particular neuroscience and technology research, then the research will be funded by an agency, contingent upon a mitigation strategy.

Through analysis of the interviews by the agency personnel and researchers, we were able to see how agencies and researchers find and resolve ethical and legal issues surrounding neuro S&T research. Especially, when the need for a particular neuro S&T outweighs the risk associated with the research. They use internal and external subject matter experts, cost-benefit analysis, risk-reducing strategies, oversight of data safety monitoring boards, and IRBs to ensure work occurs with the highest ethical standards. While we believed the responses should be very different due to the two agencies being completely different from each other, it seems in following the BRAIN initiative funding for extramural research, specifically neuro S&T research that can be translated into public use, DARPA and NIH follow a very similar path. The level of ethical and legal oversight in finding and resolving these potential issues is high and thus can be an assurance to the general public, as the researchers and agency personnel are working diligently to conduct work of the highest ethical and legal standards at both DARPA and NIH.
Public outreach programs including open call meetings and webinars are being held by neuro S&T societies. These outreach programs through agencies have potential to influence the outlook of the public and decrease their apprehension on the use of these technologies. The key is communication between the stakeholders. Thus, the fact that DARPA’s programs focus on treatments through technology, and NIH’s programs focus on health and disease treatments, becomes just the path they are taking to answer the President’s BRAIN initiative, but the guidelines, policies, and steps that they are taking to fund, participate, and address ethical, legal, and societal issues surrounding their programs are very similar. The extent of the oversight is multifaceted, with internal/external ethical and legal boards, open public meetings, involvement of all stakeholders, open door policies, internal/external education and data calls. This level of attention to issues will ensure that the transition of these technologies when released for use by the general public will go efficiently and result in being beneficial to the masses.

**Agency Policies focusing on Ethical, Legal, and Societal views surrounding Neuro S&T**

Currently, both NIH and DARPA are conducting research on neuro S&T with federal funding. A synopsis of what they are conducting and their focus on ethical, legal, and societal views in reference to these technologies and treatments is detailed below.

**NIH-Health and Disease Treatment**

Through our collected data, we have seen that neuroscience research is the largest funding bucket at NIH, with approximately, $5.4 billion/year spent on projects focused on this endeavor. This investment is split among different institutes at NIH. Research priorities are assigned as open call for science occurs and proposal are received. These proposals get reviewed and are given a score. The best ones with the highest review scores get funded, until NIH funds
are depleted. This process results in very high-quality research being funded and conducted ("Neuroethics and the NIH BRAIN Initiative." 2016).

The major goal regarding neurosciences is to understand how the brain works and to reduce the burden of illness associated with the brain ("Neuroethics and the NIH BRAIN Initiative." 2016). This makes it easy for the NIH, to set priorities. For the society in general, it is hard to understand the tragedy of the magnitude of these disorders unless you are personally affected (the numbers mean so very little to people). Society embraces the thread/numbers, but have a hard time putting their arms around these people. The goal of neuroscience research at NIH is to bring these people back into society, give them quality of life, and minimize their affliction.

This brings ethics to the fore, as it is all about risks and benefits in terms of treatments and interventions. There is a long history of ethical oversight at NIH. All funded research is conducted under IRBs, in place at hospitals, universities, etc. NIH has a high-quality process to ensure research is done in an ethical manner ("Neuroethics and the NIH BRAIN Initiative." 2016). NIH policies have adopted and learned from the tragedies that have occurred in the past. Despite the ever-changing nature of human subject-based research, we end up with many of the same issues from the past. These issues may have different flavors and energies with them, but deal with the same underlying principles and we should be able to learn from them, for example, issues such as genetic medicine, stem cells, etc.

The BRAIN Initiative focuses on the neuro basis of our behavior, which is a result of our human brain and its computing power itself. The problem is that we do not understand the computation of the brain. We currently do not have the tools to capture and understand the activities going on, and do not have rules in place to oversee them. However, if we understand
circuit activity, we can classify disorders (i.e., bipolar states, addiction, etc.). But all the neurological disorders are circuit disorders themselves (i.e., Parkinson’s disorder). NIH researchers have to first understand the science behind these circuits and then manipulate them in order to cure the diseases.

NIH has a medical focus. But some research that they participate in will also have non-medical implications. NIH has had neuroethics as part of the program from day 1. It is important that that the science does not race ahead of the ethics. NIH’s approach from the beginning has been to let core ethical standards to guide research and address ethical issues raised by new findings. The NIH published report “Brain 2025” echoes these guiding principles (“BRAIN 2025: A Scientific Vision.” 2014).

NIH believes the best way to move forward is by raising the level of conversation around the issues at hand. They routinely hold workshops to serve as a forum of discussion, have consultative function to the BRAIN project, and are taking steps towards a neuroethics grant process. NIH’s goal is to enable and accelerate work in neuroscience, before ethical issues become a roadblock to the science (“Neuroethics and the NIH BRAIN Initiative.” 2016). NIH believes that it must remain sensitive to the needs of the stakeholders and also continue to provide education around “neuro-hype” and what is and is not possible.

**DARPA-Treatment through Technological Advances**

DARPA’s mission and vision give them a main role in the BRAIN Initiative. DARPA, as an extra-mural funding agency in DoD, funds research in universities, small businesses, and foundations in the U.S. and around the world. Compared to other DoD agencies, DARPA is relatively small in size with approximately $3 billion budget annually (“Breakthrough Technologies for National Security.” 2015). With this budget, DARPA must cover a broad
spectrum of science and engineering research. Investment in the BRAIN Initiative is quite significant for DARPA. Created for the purpose of preventing strategic and technological surprise, DARPA must be out in front, pushing back the frontiers, looking forward for new technologies, looking out for new threats, and making sure that the U.S. is in front of all of these threats. Therefore, DARPA strives to build new technologies that support the national security policies/position.

Work that DARPA does often results in the society’s first interaction with the technology/product. Therefore, DARPA does not shy away from the difficult questions/issues posed by the technology, but tries to address the questions prior to funding research or introducing the technology in main-stream. DARPA is fearless but responsible in terms of exploring the frontiers (Blank 2013, 218).

So how does DARPA deal with the issues that emerge from the neuroscience and technology research? First, DARPA makes sure that they are developing the best possible technology and science to push back the frontiers and meet the goals set forth by the BRAIN initiative. Second, they recruit experts from the communities to help understand the societal aspects of the research. This work is not done in isolation; DARPA has a panel of Ethical, Legal, and Societal Issues-assessing experts to help guide. These experts review each proposal and point out all issues it might pose. These issues are mitigated and resolved prior to issuing funding.

DARPA has a neuroscience portfolio of 7 projects, each with its own specific focus. Many of these are focused on restorative therapies (function to those who have lost limbs, illnesses, and cognitive impairment following TBI). The goal is to first understand the problem and then develop tools to address the problem ("Breakthrough Technologies for National
Security.” 2015). DARPA aims to develop these technologies to help the society grapple with brain illnesses and disorders.

**Future of the BRAIN Initiative**

Both DARPA and NIH have directors that are Presidential appointees. However, they differ in their mission, vision, and structure along with Federal alignment (which changes the policies and guidelines they have to adhere to for ethical and legal issues; DARPA/DoD and NIH/DHHS). Due to 2016 election year, when data collection started, agency personnel were in the process of transitioning over to the new administration. In 2017, when the new administration took over, it was expected that some changes will follow as new Directors get appointed and the new Presidential administration sets forth its agenda on research and technology. However, to date (9 months) into the administration, DARPA and NIH have currently seen no changes occur to their BRAIN initiative portfolios. The new administration has not provided any guidance specific to the BRAIN initiative to these agencies. Whereas President Trump decided to retain the NIH Director, to date a new Director has not been appointed to DARPA.

President Trump has proposed his budget blueprint for the U.S. (“America First-A Budget Blueprint to Make America Great Again.” 2017). President Trump has proposed an 18% budget cut for NIH, reducing its proposed overall budget to $25.9 billion (Zhang 2017), where in the previous years NIH’s budget remained in the $30.5-31.5 billion range. The budget nor the President have specifically called out the BRAIN initiative, and whether funding will be provided or pulled out for the programs currently being funded through the initiative.

As discussed previously, the structure of DARPA is very different from NIH. DARPA government employees are hired on 4-year terms and thus a noticeable change is not seen in
DARPA’s BRAIN-specific administration, as program managers tend to only stay for a four-year term at DARPA. For the DoD, on the other hand, the President has proposed an increase of $52 billion in funding (“America First-A Budget Blueprint to Make America Great Again.” 2017). However, the blueprint does not specifically mention how the budget affects funding for military research and development, thus the fate of programs at military R&D agencies such as DARPA (Zhang 2017) remain uncertain at this point.

Funding for the DoD and NIH is distributed in a very different way. While the DoD is not going to see any budget cuts, DoD-funded medical research has to use all of its allocated funds or the unused funds get taken away at the end of the year. So, every year, they start out with a new funding line and know who to fund with how much. The budget cuts being proposed by the President will have a noticeably bigger impact on NIH, because approximately 75-80% of NIH’s budget is pre-allocated every year as it is carried over from grants that have already been given (Kwon 2017). Therefore, the budget cuts will impact new programs, unless the money from existing grants is reallocated to start a new program.

At the beginning of this study, we chose to explore how DARPA and NIH, two agencies that are so vastly different in their mission, vision, and structure along with Federal alignment (which changes the policies and guidelines they have to adhere to for ethical and legal issues; DARPA/DoD and NIH/DHHS), choose to participate in the BRAIN initiative. Through analysis of the data, we saw that choosing to participate in the BRAIN initiative aligned with DARPA’s and NIH’s structure, mission, and vision. NIH answered the call for participation in the BRAIN initiative by increasing the development and use of tools for acquiring fundamental insight about how the nervous system functions in health and disease. DARPA was already working on neuro S&T research, specifically funding neuro S&T research projects that focused on making
technological advances for treatments of diseases associated with the brain. However, DARPA increased their neuro S&T portfolio and answered the President’s call in taking the BRAIN initiative forward. Data that was collected via interviews with agency personnel and researchers for both agencies gave similar responses to the topics of choosing to participate and allocating funding. While we believed the responses should be very different due to the two agencies being completely different from each other, it seems in following the BRAIN initiative funding for extramural research, specifically neuro S&T research that can be translated into public use, DARPA and NIH follow a very similar path.

However, with the change in the Presidential administration and the proposed budget cuts, the future of the BRAIN initiative remains uncertain. The President is calling for reorganization of NIH’s 27 divisions and centers, which might result in merging of some centers and divisions and cutting down of programs. Therefore, funding allotted for BRAIN-specific programs might get sequestered to focus on their true mission and vision of health and disease treatment. DARPA, on the other hand, might be able to continue funding neuroscience and technology at the same pace, as their programs are specific to technological advances that directly support the military. The Trump Administration is calling for advances in the U.S.’s military, so DARPA’s neuro S&T portfolio might not get impacted. Making claims of declaration at this time will be premature; only as time passes and the budget gets passed through Congress will we see the true impact of the changes that occur at Presidential appointed agencies due to the administration change. To date, DARPA and NIH have reported no changes to their BRAIN initiative portfolio and therefore are operating under the same guidelines as the previous Presidential administration.
Policy Implications

Through this analysis, there are several policy issues that were noted. These policy problems will need to be addressed as these technologies become mainstream, such as justice, fairness, equal distribution among all, autonomy, freedom, responsibility, etc. (Blank 2013, 78). We know that unfair distribution can potentially lead to more problems than good. Therefore, careful planning and thought has to be given as to how insurance companies, including Medicaid and the Affordable Care Act, will deal with these new treatments and technologies.

The nature of neuro S&T research has changed from the primitive to the new way. The crude perception of researchers conducting lobotomies has been shifted to new issues. While some of these issues tend to be less intrusive (in some cases), they have the potential to change the value system of our society (Blank 2013, 78). As discussed by Robert Blank (Blank 2013, 79), policy issues for neuroscience are relevant and must be addressed due to three dimensions:

1. Decisions have to be made, due to involvement of public funds, where input in the decision-making process from the general public is imperative.

2. While governmental intervention in the medical arena is usually limited and not necessary, if a technology/treatment is truly beneficial and a great benefit to society, and if the government tries to entice the public with tax incentives, educational programs, etc., could that be a way to go? Should the government be providing encouragement in this area?

3. Consequences incurred based on the use of neuro S&T. For example, if we start using neural imaging to type personalities, will this end up affecting how individuals receive jobs? How about in legal proceedings? This is something that needs to be addressed through policy making.
Through our analysis of neuro S&T research and how it is being funded and researched, several recommendations can be made to agency personnel and researchers in moving forward:

1. Post-trial obligations should be enforced upon by agencies funding the research, in order to continue providing care or follow up care to ensure unintended side effects did not occur over a period of time through the researcher.

2. Provide continual access to treatment or medicine through clinicians up to at least 5-10 years, post end of research trial, to ensure subject is under constant medical care or has access to medical care if needed.

3. Agencies should ensure that policies developed promote responsible conduct of both development and distribution of neuro S&T research (Anderson et al. 2012, 298).

4. Development of scenarios (which is already occurring in some programs, but should be made mandatory for all programs) to understand the broad social impact of these technologies and their effects.

5. Special consideration must be placed on “human values” (autonomy, freedom, equity, etc.) when funding these technologies.

Communication between stakeholders, and timely addressing of issues listed in previous sections through policies, can lead to an increase in the public trust in these technologies. This study made it clear that agencies and researchers are very cautious about funding neuro S&T research. They have set up several checks and balances within agencies and research institutes to ensure all funded research occurs with the highest ethical and legal standards and increases the positive societal impact of these technologies. Since most of these devices are currently in their novice stages of development, their full impact on society will not be known until full
deployment into society. Therefore, careful consideration of policies that address and place emphasis on the “human values” will ensure a positive impact on the society.
CHAPTER 8

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Appendix A

Decade of the Brain: Presidential Proclamation 6158 (Library of Congress)

Project on the Decade of the Brain

Presidental Proclamation 6158

July 17, 1990
By the President of the United States of America
A Proclamation

The human brain, a 3-pound mass of interwoven nerve cells that controls our activity, is one of the most magnificent-and mysterious--wonders of creation. The seat of human intelligence, interpreter of senses, and controller of movement, this incredible organ continues to intrigue scientists and layman alike.

Over the years, our understanding of the brain--how it works, what goes wrong when it is injured or diseased--has increased dramatically. However, we still have much more to learn. The need for continued study of the brain is compelling: millions of Americans are affected each year by disorders of the brain ranging from neurogenetic diseases to degenerative disorders such as Alzheimer's, as well as stroke, schizophrenia, autism, and impairments of speech, language, and hearing.

Today, these individuals and their families are justifiably hopeful, for a new era of discovery is dawning in brain research. Powerful microscopes, major strides in the study of genetics, and advances in brain imaging devices are giving physicians and scientists ever greater insight into the brain. Neuroscientists are mapping the brain's
biochemical circuitry, which may help produce more effective drugs for alleviating the suffering of those who have Alzheimer's or Parkinson's disease. By studying how the brain's cells and chemicals develop, interact, and communicate with the rest of the body, investigators are also developing improved treatments for people incapacitated by spinal cord injuries, depressive disorders, and epileptic seizures. Breakthroughs in molecular genetics show great promise of yielding methods to treat and prevent Huntington's disease, the muscular dystrophies, and other life-threatening disorders.

Research may also prove valuable in our war on drugs, as studies provide greater insight into how people become addicted to drugs and how drugs affect the brain. These studies may also help produce effective treatments for chemical dependency and help us to understand and prevent the harm done to the preborn children of pregnant women who abuse drugs and alcohol. Because there is a connection between the body's nervous and immune systems, studies of the brain may also help enhance our understanding of Acquired Immune Deficiency Syndrome.

Many studies regarding the human brain have been planned and conducted by scientists at the National Institutes of Health, the National Institute of Mental Health, and other Federal research agencies. Augmenting Federal efforts are programs supported by private foundation and industry. The cooperation between these agencies and the multidisciplinary efforts of thousands of scientists and health care professionals provide powerful evidence of our nation's determination to conquer brain disease.
To enhance public awareness of the benefits to be derived from brain research, the Congress, by House Joint Resolution 174, has designated the decade beginning January 1, 1990, as the "Decade of the Brain" and has authorized and requested the President to issue a proclamation in observance of this occasion.

Now, Therefore, I, George Bush, President of the United States of America, do hereby proclaim the decade beginning January 1, 1990, as the Decade of the Brain. I call upon all public officials and the people of the United States to observe that decade with appropriate programs, ceremonies, and activities.

In Witness Whereof, I have hereunto set my hand this seventeenth day of July, in the year of our Lord nineteen hundred and ninety, and of the Independence of the United States of America the two hundred and fifteenth.

GEORGE BUSH

[Filed with the Office of the Federal Register, 12:11 p.m., July 18, 1990]
BRAIN Initiative

President Obama is making new investments in the “BRAIN” Initiative — a bold new research effort to revolutionize our understanding of the human mind and uncover new ways to treat, prevent, and cure brain disorders like Alzheimer’s, schizophrenia, autism, epilepsy, and traumatic brain injury.

THE WHITE HOUSE IS ANNOUNCING
OVER $300 MILLION IN PUBLIC AND PRIVATE INVESTMENTS
IN SUPPORT OF THE BRAIN INITIATIVE

Since President Obama announced the BRAIN Initiative in April 2013, dozens of leading technology firms, academic institutions, scientists and other key contributors to the field of neuroscience have answered his call and made significant commitments to advancing the Initiative.
Building off of $100 million in commitments announced last year at NIH, NSF and DARPA, the BRAIN Initiative is growing to five participating federal agencies with the addition of FDA and IARPA.

NIH
NATIONAL INSTITUTES OF HEALTH

NIH is announcing $46 million in new BRAIN-related grant awards, focusing on new tools and techniques.

FDA
FOOD AND DRUG ADMINISTRATION

FDA is joining the BRAIN Initiative, with the goal to enhance the transparency of the regulatory landscape for neurological medical devices.

DARPA
DEFENSE ADVANCED RESEARCH PROJECTS AGENCY

DARPA is building on four existing programs and is planning new investments in the BRAIN Initiative, with the ultimate goal of relieving and rehabilitating warfighters and civilians suffering from traumatic injury and neuro-psychiatric illness.

IARPA
INTELLIGENCE ADVANCED RESEARCH PROJECTS ACTIVITY

IARPA is joining the BRAIN Initiative and will use multidisciplinary approaches to advance understanding of cognition and computation in the brain.

NSF
NATIONAL SCIENCE FOUNDATION

NSF is continuing to make investments to support BRAIN Initiative by accelerating fundamental research and the development of new technologies for neuroscience and neuroengineering.
NOW IS THE TIME TO INVEST IN BRAIN RESEARCH

POSSIBLE LONG-TERM OUTCOMES

The BRAIN Initiative has the potential to do for neuroscience what the Human Genome Project did for genomics by supporting the development and application of innovative technologies that can create a dynamic understanding of brain function. It aims to help researchers uncover the mysteries of brain disorders, such as Alzheimer's and Parkinson's diseases, depression, Post-Traumatic Stress Disorder (PTSD), and traumatic brain injury (TBI).

Ongoing and new private sector partners are making commitments to support the BRAIN Initiative. We encourage even more companies, universities and philanthropists to get involved.

PRIVATE SECTOR COMMITMENTS

$30 MILLION US PHOTONICS INDUSTRY

$5 MILLION

GOALS

To develop new optics and photonics technologies to tackle challenges of the BRAIN Initiative
PRIVATE RESEARCH EFFORTS

$65 MILLION
UNIVERSITY OF PITTSBURGH

Creating a new University of Pittsburgh Brain Institute focused on unlocking the mysteries of normal and abnormal brain function

$12 MILLION
UNIVERSITY OF CALIFORNIA, BERKELEY AND CARL ZEISS MICROSCOPY

Infrastructure for neurotechnology development

$40 MILLION
THE CARNEGIE MELLON UNIVERSITY

Commitment to support the goals of the BRAIN Initiative

$62 MILLION
THE SIMONS FOUNDATION

To uncover patterns of the neural activity that produce cognition by combining analyses of internal mental states with studies of sensory and motor processing.

Continuing Progress from Existing Partners

$60 MILLION
ANNUALLY
THE ALLEN INSTITUTE FOR BRAIN SCIENCE

Understand how brain activity leads to perception, decision making and ultimately action

$70 MILLION
HOWARD HUGHES MEDICAL INSTITUTE

Develop new imaging technologies and understand how information is stored and processed in neural networks

$40 MILLION

Fund innovative peripheral neurotechnologies and provide unrestricted, royalty-free access for research purposes to all intellectual property developed through this challenge.
In May 2014, at the President’s request, the Presidential Commission for the Study of Bioethical Issues released the first of two reports exploring core ethical standards to guide the BRAIN Initiative and other recent advances in neuroscience.

The Human Genome Project demonstrates the potential impact that ambitious research programs like the BRAIN initiative can have. From 1988-2003, the Federal Government invested $3.8 billion in the Human Genome Project, which has since generated an economic output of $796 billion—a return of $141 for every $1 invested.

LEARN MORE AT WHITEHOUSE.GOV/BRAIN
Appendix C

Whom to Contact about this study:
Principal Investigator: Sahar Zafar
Department: Public Administration
Telephone number: 410-591-2998

CONSENT FORM FOR PARTICIPATION IN RESEARCH ACTIVITIES

“Ethical, Legal and Societal Implications of Neuroscience and Technology Research and its Impact on Public Policy”

I. INTRODUCTION/PURPOSE:
I am being asked to participate in a research study. The purpose of this study is to address how neuroscience and technology research addresses significant societal barriers to its public distribution and use. I am being asked to volunteer because my agency is currently participating in the BRAIN initiative. My involvement in this study will begin when I agree to participate and will continue until the questionnaire ends. About 3-15 individuals from your agency will be invited to participate.

II. PROCEDURES:
As a participant in this study, I will be asked to answer a questionnaire. There will be no personally identifiable information collected. The researcher is only collecting demographic information for data analysis purposes. My participation in this study is voluntary.

III. RISKS AND BENEFITS:
My participation in this study does not involve any significant risks and I have been informed that my participation in this research will not benefit me personally, but outcome of study will benefit others, the community or society.

IV. CONFIDENTIALITY:
Any information learned and collected from this study in which I might be identified will remain confidential and will be disclosed ONLY if I give permission. All personally identifiable data will be stored on a secure network with access protection. Only the investigator and members of the research team will have access to these records. If information learned from this study is published, I will not be identified by name. By signing this form, however, I allow the research study investigator to make my records available to the University of Baltimore Institutional Review Board (IRB) and regulatory agencies as required to do so by law.
Consenting to participate in this research also indicates my agreement that all information collected from me individually may be used by current and future researchers in such a fashion that my personal identity will be protected. Such use will include sharing anonymous information with other researchers for checking the accuracy of study findings and for future approved research that has the potential for improving human knowledge.

V. **SPONSOR OF THE RESEARCH:**
This research study is for a doctoral dissertation.

VI. **COMPENSATION/COSTS:**
My participation in this study will involve no cost to me. There is no compensation being provided to participate in this study.

VII. **CONTACTS AND QUESTIONS:**
The principal investigator, Sahar Zafar, has offered to and has answered any and all questions regarding my participation in this research study. If I have any further questions, I can contact Sahar Zafar, at (410-591-2998, szafar84@gmail.com) or her dissertation chair, Dr. Lenneal Henderson, at (410-837-6198, lhenderson@ubalt.edu). For questions about rights as a participant in this research study, contact the UB IRB Coordinator: 410-837-6199, irb@ubalt.edu.

VIII. **VOLUNTARY PARTICIPATION**
I have been informed that my participation in this research study is voluntary and that I am free to withdraw or discontinue participation at any time.

*I will be given a copy of this consent form to keep.*

IX. **SIGNATURE FOR CONSENT**
The above-named investigator has answered my questions and I agree to be a research participant in this study. By signing this consent form, I am acknowledging that I am at least 18 years of age.

Participant’s Name: ___________________________ Date: ______________________

Participant’s Signature: ________________________ Date: ______________________

Investigator's Signature: ________________________ Date: ______________________
Appendix D
Researcher Copy with Prompts

Questionnaire directed towards Agency Personnel at DARPA and NIH

Demographic Information

<table>
<thead>
<tr>
<th>Sex</th>
<th>Male</th>
<th>Female</th>
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<tbody>
<tr>
<td>Age:</td>
<td>18-29</td>
<td>30-49</td>
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<td>Education:</td>
<td>College Graduate</td>
<td>Post-Graduate</td>
</tr>
<tr>
<td>Ethnicity/Race:</td>
<td>White</td>
<td>Black</td>
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1. How did your agency decide to participate in the BRAIN initiative? On what basis is it decided to pursue neuroscience and technology, as opposed to competing health research initiatives?
   - Mission and Vision Alignment
   - Based on Funding allocated by Office of Management and Budget
   - Other, please explain:

2. How did (if) the agency’s approach to neuroscience and technology research change following the announcement of the President Obama’s “BRAIN” initiative?
   - No change
   - Yes, changed. Please explain:

3. How is funding allocated within your agency for new proposed neuroscience and technology projects? What criteria is considered to award a project?
   - Based on Congressional Mandates. Please explain how criteria is established:
   - Based on Need for Technology. Please explain how criteria is established:
   - Other, please explain:

4. How are potential barriers (concerns about whether the research should be pursued) raised, addressed, and resolved/not resolved? Where do these barriers tend to rise?
   - Within the Agency, particular office:
   - Externally, please specify:
   - Other, please explain:
5. How is your agency addressing the ethical issues, (such as autonomy, freedom, and fairness) surrounding neuroscience and technology research?
   - Utilizing External Institutional Review Boards
   - Implementing Internal Ethical and Regulatory Oversight
   - Other, please explain: ______________________________________________________

6. How is your agency addressing the legal issues, (such as justice, and fairness) surrounding neuroscience and technology research?
   - External Legal Oversight
   - Internal Legal Oversight
   - Other, please explain: ______________________________________________________

7. How is your agency addressing the societal issues, (such as fair and equal distribution of goods) surrounding neuroscience and technology research?
   - External Oversight to Ensure Unbiased Enrollment/Distribution
   - Internal Oversight to Ensure Unbiased Enrollment/Distribution
   - Other, please explain: ______________________________________________________

8. Have you noticed a change with how the new Presidential administration is managing the BRAIN initiative?
   a. No change.
   b. Yes, changed. Please explain:
      _______________________________________________________________________

Researcher Copy with Prompts

Interview Questions directed towards Researchers at DARPA and NIH

Demographic Information

Sex: Male Female
Age: 18-29 30-49 50-64 65+
Education: College Graduate Post-Graduate Ph.D. or M.D.
Ethnicity/Race: White Black Non-White (incl. Hispanics)

1. Based on the program that you are working on, what ethical issues (such as autonomy, freedom, and fairness) surround your research? Please explain:

2. Based on the program that you are working on, what legal issues (such as such as justice, and fairness) do you anticipate or currently surround your research? Please explain:

3. Based on the program that you are working on, what societal issues (such as fair and equal distribution of goods) do you anticipate or currently surround your research? Please explain:
4. In your opinion, how can these ethical, legal and societal issues be mitigated, especially prior to these technologies being made available to the general public? Please explain:

5. How are issues of outside reactions (public perception and/or opinion) on neuroscience and technology researcher handled?

6. How are potential barriers (concerns with the research) raised, addressed, resolved/not resolved? Where do most of these barriers arise? Internally or externally? Please explain.

7. In your opinion, you think that the use of neuroscience and technologies will face resistance by the general public? Please explain:

**Questionnaire directed towards Agency Personnel at DARPA and NIH**

**Demographic Information**

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2. How did (if) the agency’s approach to neuroscience and technology research change following the announcement of the President Obama’s “BRAIN” initiative?

3. How is funding allocated within your agency for new proposed neuroscience and technology projects? What criteria is considered to award a project?

4. How are potential barriers (concerns about whether the research should be pursued) raised, addressed, and resolved/not resolved? Where do these barriers tend to rise?

5. How is your agency addressing the ethical issues, (such as autonomy, freedom, and fairness) surrounding neuroscience and technology research?

6. How is your agency addressing the legal issues, (such as justice, and fairness) surrounding neuroscience and technology research?

7. How is your agency addressing the societal issues, (such as fair and equal distribution of goods) surrounding neuroscience and technology research?

8. Have you noticed a change with how the new Presidential administration is managing the BRAIN initiative?
Interview Questions directed towards Researchers at DARPA and NIH

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1. Based on the program that you are working on, what ethical issues surround your research? Please explain:

2. Based on the program that you are working on, what legal issues do you anticipate or currently surround your research? Please explain:

3. Based on the program that you are working on, what societal issues do you anticipate or currently surround your research? Please explain:

4. In your opinion, how can these ethical, legal and societal issues be mitigated, especially prior to these technologies being made available to the general public? Please explain:

5. How are issues of outside reactions (public perception and/or opinion) on neuroscience and technology researcher handled?

6. How are potential barriers (concerns with the research) raised, addressed, resolved/not resolved? Where do most of these barriers arise? Internally or externally? Please explain.

7. In your opinion, you think that the use of neuroscience and technologies will face resistance by the general public? Please explain:
June 28, 2016

Sahar Zafar  
University of Baltimore  
1420 N. Charles Street Baltimore,  
MD 21201

Dear Ms. Zafar:

This letter serves as official confirmation of the Institutional Review Board’s review of your protocol for a study entitled “Ethical, Legal and Societal Implications of Neuroscience and Technology Research and its Impact on Public Policy,” submitted for review on June 18, 2016.

The Institutional Review Board considered your request and concluded that your protocol poses no more than minimal risk to participants. In addition, research involving the use of widely acceptable survey/interview procedures where the results are kept confidential and the questions pose minimal discomfort to participants is exempt from IRB full committee review per 45 CFR 46.101 (b) (2). As a result, the Institutional Review Board has designated your proposal as exempt.

Investigators are responsible for reporting in writing to the IRB any changes to the human subject research protocol, measures, or in the informed consent documents. This includes changes to the research design or procedures that could introduce new or increased risks to human subjects and thereby change the nature of the research. In addition, you must report any adverse events or unanticipated problems to the IRB for review.

If you have any questions, please do not hesitate to contact me directly by phone or via email.

As authorized by P. Ann Cotten, C.P.A., D.P.A.

Chair, Institutional Review Board

Matthew D. Poland, CRA  
Coordinator, Institutional Review Board

cc: L. Henderson