On August 3, 2016, the Neuroethics Workgroup of the NIH Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Multi-Council Working Group (MCWG) held its second in-person meeting in Washington, DC. The Workgroup discussed progress made since the first meeting (which occurred on February 9, 2016) along with plans for next steps, including Workgroup deliverables. In order to understand how different groups incorporate neuroethics into their work, presentations were given by NIH’s four partner federal agencies participating in the BRAIN Initiative (Food and Drug Administration, Defense Advanced Research Projects Agency, Intelligence Advanced Research Projects Activity, and National Science Foundation). The Executive Director of the Presidential Commission for the Study of Bioethical Issues also gave a presentation on the Commission’s outreach activities. The meeting also included participants from the Human Brain Project and Georgetown University.

Welcome and introductions
Dr. Walter Koroshetz, Director of the National Institute of Neurological Disorders and Stroke and Co-Director of the NIH BRAIN Initiative, opened the day by welcoming all of the participants, stating that neuroethics crosscuts all the organizations involved in the BRAIN Initiative and underscoring the importance of cooperative efforts to integrate ethics into all aspects of neuroscience research. He observed that while many of the ethical questions and issues to be discussed are not new, new technologies bring existing questions into sharp relief. Also, addressing ethical issues raised by BRAIN Initiative research should move forward in an iterative process, integrated with scientific progress itself. Otherwise, there is risk for new technologies to ‘get ahead’ of the ethical and societal considerations.

Dr. Koroshetz reiterated the original charge to the Workgroup, with particular emphasis on a few points:
- Identify ethical issues of importance in funded BRAIN research;
- Consider long term concerns, recognizing that many of these questions don’t have answers yet and would benefit from community dialogue and engagement; and
- Identify ethical questions raised by BRAIN Initiative projects that point to a need for neuroethics research.

He concluded by giving an overview of BRAIN Initiative research progress to-date.

Neuroethics Workgroup co-chairs Hank Greely and Dr. Christine Grady added to the introduction by summarizing the structure of the Workgroup and its purpose in providing insight to the MCWG on neuroethics issues directly relevant to research supported by the BRAIN Initiative. They both emphasized that the Workgroup is new and still in the process of finding the best way to be effective.

Presentation and discussion on data sharing and cyber security
Dr. Greg Farber (National Institute of Mental Health) gave a presentation on the BRAIN Initiative’s current plans for handling storage, sharing, and security of the vast amounts of data expected to be generated by NIH BRAIN-funded research. At the MCWG’s meeting on August 2\textsuperscript{nd}, 2016, they approved a funding opportunity concept to devise standards defining experimental parameters, data archives for the research community, and software tools for data analysis. Current existing archives, such as the NIMH Data Archive, use de-identified data from human subjects and strict access rules to protect the security of human data deposited therein, including genomic, imaging, clinical, and demographic
information. However, new technologies with greater resolution of imaging, increased data from implanted devices, and videos of a person’s real-time response to brain stimulation therapy may make data increasingly difficult to de-identify, and create a greater concern for cybersecurity and privacy. Dr. Farber touched on a range of potential ethical issues, including finding a balance between individual privacy and allowing access to data for research; stigma associated with identification of individuals with mental health disorders; and the safety and usage of non-invasive modulatory devices for non-medical purposes.

Update on past and future neuroethics meetings
Workgroup members and meeting participants were encouraged to give an update on any neuroethics-related meeting they recently attended, or plan to attend in the near future. These updates underscore the growing interest and activity in neuroethics around the world.

• **Neuroethics Network – Going Global and Facing the Future**
  o Held in Paris, France, June 29 - July 1, 2016
  o A project of the Neuroscience, Éthique et Société Association and hosted by ICM (Institut du Cerveau et de la Moëlle Épinière) in Paris
  o Attended by Karen Rommelfanger and Khara Ramos
  o Khara spoke on a panel about big neuroscience initiatives; Karen spoke on a panel about her placebo research
  o The meeting promoted the exchange of ideas focused on key issues in brain science in an international forum

• **Our Brains, Ourselves, and Our World (O3)**
  o Attended by Hank Greely and Steve Hyman
  o A private academic effort, with the goal of bringing a global focus to neuroethics and learning different perspectives on these issues from different countries
  o Included representatives from South America, South Asia, and South Africa, who spoke to how ethics is interpreted in different parts of the world

Upcoming meetings
• **Neurotechnology and Society: Strengthening Responsible Innovation in Brain Science**
  o Washington, DC, September 15-16, 2016
  o Organized by the Organization for Economic Cooperation and Development
  o Several Workgroup members and NIH staff will be speaking:
    ▪ Holly Lisanby (NIMH) and Hank Greely – panel session on non-invasive neuromodulation
    ▪ Walter Koroshetz, Justin Sanchez, Miyoung Chun – panel session on the role of funders and investors
    ▪ Khara Ramos – panel session on programs in brain research and neurotechnology connecting scientific and social outcomes

• **International Neuroethics Society**
  o San Diego, CA, November 10-11, 2016
  o Annual meeting held in conjunction with the annual meeting of the Society for Neuroscience
  o Several Workgroup members and NIH staff will be speaking:
• Steven Hyman – distinguished neuroethics lecture
• Walter Koroshetz – plenary speaker
• Nita Farahany – panel session on ethics of emerging technologies
• Karen Rommelfanger – panel session on a therapeutic neurotechnology case study
• Khara Ramos – International Ambassador session

• Society for Neuroscience (SfN)
  o San Diego, CA, November 12-16, 2016
  o Several specific neuroethics sessions and workshops will be available to attend

Identifying potential non-federal workgroup partners
The group discussed potential non-federal partners with a shared interest in the workgroup’s efforts and objectives.

Human Brain Project (HBP)
Dr. Jean-Pierre Changeux and Dr. Arleen Salles updated the group on the Human Brain Project’s current efforts related to ethics. The HBP aims to build a research infrastructure for brain research, cognitive neuroscience, and brain-inspired computing. Drs. Changeux and Salles described progress within the HBP Ethics and Society Subproject, and the Foresight Lab at King’s College London, which is part of this subproject.

The International Neuroethics Society (INS)
The mission of the INS is to promote the development and responsible application of neuroscience through interdisciplinary and international research, education, outreach, and public engagement. The INS recently established a Response Action Task Force (RATF) to anticipate and respond to issues at the intersection of neuroscience and society. The RATF could serve as a partner to the Workgroup, providing an expert opinion on key ethical issues of interest.

Academic Partners
Academic institutions suggested for partnership included Emory, Duke, Stanford, and the University of Pennsylvania, each of which has a center or program focused on neuroethics.

Discussion of workgroup deliverables
Workgroup members and participants discussed how to proceed with development of different types of deliverables. The Workgroup built on ideas from their February 9, 2016, meeting. Ideas included:
• Whitepapers or issue briefs
• Topical workshops
• One-pagers to help guide neuroscientists; topics to include: What is neuroethics? What role does neuroethics have in a neuroscience grant/project?

President’s Bioethics Commission outreach activities
Dr. Lisa M. Lee, Executive Director of the Presidential Commission for the Study of Bioethical Issues, explained how the Commission has approached the goal of expanding outreach and interest in bioethics with the larger scientific community as well as the public. This commission is the first presidential bioethics commission to exist during the modern social media era, and they took advantage of new ways of leveraging social media tools to amplify their reach and impact. The commission has held a series of
in-person talks, teaching demonstrations, small group briefings, and training to generate materials to be archived and accessed by anyone, and each of these events is recapitulated in a blog post, tweet, and email to reach a broader audience than ever before. All of their efforts can be found on the Commission’s website, www.bioethics.gov.

**Updates from federal BRAIN Partners**

During this portion of the meeting, NIH’s partner federal agencies involved with the BRAIN Initiative were asked to provide an update on any neuroethics-relevant activities.

**Justin Sanchez (DARPA)**

Dr. Sanchez discussed DARPA’s efforts towards integrating ethical, legal, and societal implications (ELSI) of new technologies into their BRAIN-funded research, through a neuroethics ELSI panel. A member of that panel, Dr. Jim Giordano, discussed a recently developed operational neurotechnology risk assessment and mitigation paradigm (ON-RAMP), which entails querying, framing, and modeling patterns and trajectories of neuroscience and neurotechnology research and translational uses, and the ELSI generated by such advancements and their applications. Recently DARPA held an agency-wide event in Saint Louis (”Wait, What?”), which served as a forum on future technologies, on their potential to radically change how we live and work, and on the opportunities and challenges these technologies will raise within the broadly defined domain of national security.

**Alexis Jeannotte (IARPA)**

Dr. Jeannotte explained that IARPA has a smaller footprint for programs that intersect with neurotechnology, and focuses more on human neuroscience and enhancement. Dr. Jeannotte added that IARPA is concerned with the ethical aspects of research application in addition to ethical conduct of research, especially regarding dual use. She expressed interest that a partnership with the Neuroethics Workgroup will aid incorporation of neuroethics into their research programs.

**Howard Nusbaum (NSF)**

Dr. Nusbaum relayed that the science funded by the NSF is basic research, and ethical considerations are typically folded into institutional review boards and institutional animal care and use committees. He noted that NSF program officers engage in conversations with funded researchers about the ethical conduct of science, data use, and publication. Dr. Nusbaum reaffirmed that NSF is interested in engaging further in neuroethics conversations and possibly supporting future neuroethics workshops.

**William Heetderks, Devjani Saha (FDA)**

Dr. Saha explained that the FDA’s interest in neuroethics centers on moving neurological devices from bench to market, and concerns for clinical decisions involving individual preferences, quality of life, and long-term responsibilities of implanted devices. The FDA is a regulatory agency that focuses on safety and effectiveness and uses several existing tools to incorporate ethics into policy, including informed consent, clinical protocols, risk/benefit assessment, and advisory panels. Dr. Saha offered several action items that the FDA could provide to inform the Neuroethics Workgroup, including 1) a resource sheet focusing on FDA policy as it pertains to ethics, 2) co-hosting an ethics webinar, and 3) developing a joint manuscript for publication on neuroethics and regulatory policy.