Brain Research Through Advancing Innovative Neurotechnologies® (BRAIN) Neuroethics Working Group (NEWG) Workshop on Continuing Trial Responsibilities

Part 1 Virtual Agenda - Tuesday, May 24, 2022

Zoom Session (Times are ET) - Open to the Public

12:00 PM **Welcome**
John Ngai, PhD – Director, NIH BRAIN Initiative

12:05 PM **Introduction and background**
Saskia Hendriks, MD, PhD – Clinical Center, NIH

12:15 PM **Panel 1: What needs may study participants have in relation to their trial participation, after a trial ends?**

- Brandy Ellis
  - Patient-Participant
- Jen French
  - Executive Director, Neurotech Network
- Gabriel Lázaro-Muñoz, PhD, JD
  - Assistant Professor, Center for Bioethics at Harvard Medical School
- James Mahoney, PhD
  - Assistant Professor/Clinical Neuropsychologist, West Virginia Univ

1:15 PM **Panel 1 Discussion:** Co-Moderators: Winston Chiong, MD, PhD + Nina Hsu, PhD

1:45 PM **BREAK**

2:30 PM **Panel 2: What do different stakeholders currently provide, and what can/could they provide in terms of research-related care needs?**

- Yagna Pathak, PhD
  - Staff Research Scientist, Abbott Neuromodulation
- Martha Morrell, MD
  - Stanford University
- Carl Li, MD
  - Medical Officer, Centers for Medicare & Medicaid Services (CMS)
- Rhonda Robinson Beale, MD
  - SVP Deputy Chief Medical Officer, United Health Group
- Shirley McCartney, PhD
  - Director, Clinical Research Neurological Surgery, OHSU
- Nick Langhals, PhD
  - Program Director, Division of Translational Research, NINDS

4:00 PM **Panel 2 Discussion:** Co-Moderators: Sameer Sheth, MD, PhD + Nina Hsu, PhD

4:45 PM **Day 1 wrap up**

5:00 PM **Adjourn**

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Part 2 Virtual Agenda - Wednesday, May 25, 2022

Zoom Session (Times are ET) - Open to the Public

12:00 PM **Welcome**
John Ngai, PhD – Director, NIH BRAIN Initiative

12:05 PM **Recap of Day 1**
Nina Hsu, PhD

12:30 PM **Panel 3: What should be the minimum in research-related care that should be facilitated in implanted neural device trials? When would stakeholders have responsibilities to provide or facilitate more than the previously defined minimum?**

- Tracy Dixon-Salazar, PhD
  - Executive Director, LGS Foundation
- Patricio Riva Posse, MD
  - Assistant Professor, Emory University
- Sara Goering, PhD
  - Professor of Philosophy and the Program on Ethics, U Washington
- Ishan Dasgupta, JD, MPH
  - Fellow, Neuroscience & Society, Dana Foundation
- Luann E. Van Campen, PhD, MA
  - Founder and President, Ethics Matters LLC
- John Marler, MD
  - Acting Clinical Deputy Director, Division of Neurological and Physical Medicine Devices, Center for Devices and Radiological Health, US Food and Drug Administration

1:45 PM **Panel 3 Discussion:** Co-Moderators: Christine Grady, MSN, PhD, + Saskia Hendriks, MD, PhD

2:30 PM **BREAK**

3:00 PM **Forum with all stakeholders**

i. **What are the gaps between what is currently facilitated and what is sufficient/appropriate? How can we best fill those gaps?**
   Co-moderators: Hank Greely, JD, and Saskia Hendriks, MD, PhD

4:30 PM **Day 2 wrap up**

4:45 PM **Adjourn**