NIH pairs cutting-edge neuroethics with ground-breaking neurotechnologies

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With support from the National Institutes of Health's Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, scientists are developing powerful new devices and technologies to monitor and regulate brain activity. To ensure NIH keeps pace with rapid technological development and help clinicians and researchers ethically fit these new tools into practice, a paper recently published in *JAMA Neurology* highlights potential issues around and offers recommendations about clinical research with both invasive and noninvasive neural devices.

"NIH is leading the way for proactively considering and addressing potential ethical considerations as the BRAIN Initiative leads to novel ways of measuring and influencing the activity of the brain," said Walter Koroshetz, M.D., director of the NIH's National Institute of Neurological Disorders and Stroke (NINDS). "Having discussions in real time is of paramount importance as clinical researchers investigate the use of such tools to reduce the burden of brain disease."

Considerable attention has been given recently to neural devices, which can be used to record or alter brain activity. In some cases, they are implanted within the brain for the purpose of stimulating or inhibiting specific regions to treat a disorder. Recent high profile investments in neural device companies have increased public attention to an already promising field of study. However, it is crucial that doctors and industry emphasize protection of research participants as they conduct trials to test and optimize these devices.

By bringing together neuroscience researchers, clinicians, and ethicists, the NIH is supporting an effort to address the ethical challenges associated with clinical research advances. Shortly after the launch of the BRAIN Initiative in 2013, the NIH BRAIN Initiative's Neuroethics Working Group was formed as a working group of the NINDS Advisory Council to recommend approaches for identifying and addressing ethical questions raised by the development and use of the resulting tools and technologies.

"Cutting-edge science requires cutting-edge ethics." said Khara Ramos, Ph.D., Director of Neuroethics at NINDS and co-author of the paper. "The BRAIN Initiative is moving the field of neuroscience forward at a rapid pace, and we are fortunate to collaborate with experts from diverse backgrounds to help us evaluate and anticipate the ethical implications of that research."

In their paper, the authors discuss three main areas of ethical challenges related to neural devices. Two of these build upon established issues: weighing the risks and benefits involved in clinical experimentation and the importance of informed consent—whether a trial participant is provided with enough information, and under the right circumstances to be able to decide on enrolling.

The third area of focus is relatively new for these devices: what responsibilities do researchers, manufacturers, and funders have to the research participants once a trial has ended? Unlike participation in most drug trials, individuals who participate in a device trial often walk away with long-lasting changes—invasive brain implants or other devices—that have an impact on their future. Who is responsible for making sure that the implant or device continues to work properly weeks, months, or years later? The authors suggest that, at a minimum, researchers and those who fund that research need to anticipate any future care needs trial participants may have, including associated costs.

The paper looks at some of those needs including long-term maintenance (such as repairs, battery replacement, and software updates), the care required for possible adverse effects that could arise after the trial, and long term support by manufacturers who may continue to improve their devices based on research or commercial interests.

"This important research is only possible through the generosity and trust of human research participants, many of whom are themselves patients seeking treatment for serious neurological conditions," said Winston Chiong, M.D., Ph.D., associate professor in residence, University of California, San Francisco Neurology and co-author of the paper. "It's very important that this research is guided not only by researchers' good intentions, but also by deliberate consideration about present and future risks to participants. This also includes considerations of cost and broader practical questions about what it's like to live with one of these devices."

More information: Saskia Hendriks et al, Ethical Challenges of Risk, Informed Consent, and Posttrial Responsibilities in Human Research With Neural Devices, *JAMA Neurology* (2019). DOI: 10.1001/jamaneurol.2019.3523

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