



GLOBAL NEUROETHICS SUMMIT | 2017

EXISTING NEUROETHICS GUIDELINES

A source of summarized aims and results of workshops, conferences, etc. that have provided currently existing neurotechnology guidelines

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Abbreviations:

- CED** = cognitive enhancement device
- HPE** = human performance enhancement
- DBS** = deep brain stimulation
- BCI** = brain-computer interface

Meeting/Source

Grand Challenges for Global Brain Sciences (Global Brain Workshop, 2016) https://arxiv.org/ftp/arxiv/papers/1608/1608.06548.pdf	Aims: <ul style="list-style-type: none">• Discussion with 60+ scientists from around the world to identify grand challenges (significant, feasible, inclusive) for global brain sciences
	Outcomes: <ul style="list-style-type: none">• 3 grand challenges: (1) create virtual “NeuroZoo” by mapping brains of multiple species to determine what makes human brains unique, (2) produce multiscale models of neural systems from coordinated investigation within naturalistic environments to understand how the brain solves complex computational problems, and (3) augment clinical-decision making by incorporating neural mechanisms of dysfunction• Plans for deploying universal-cloud resource of data for the grand challenges and steps to enhance cross-cultural understanding and collaboration to fuel global brain sciences





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<p>Proceedings of the Fourth Annual Deep Brain Stimulation Think Tank: A Review of Emerging Issues and Technologies</p> <p>(Deeb et al., 2016)</p> <p>https://www.ncbi.nlm.nih.gov/pubmed/27920671</p>	<p>Aims:</p> <ul style="list-style-type: none">• Review current progress in technological advances and use of DBS to treat neurological and neuropsychiatric disorders <p>Outcomes:</p> <ul style="list-style-type: none">• Updated state of research, new findings, and discussion on policy and regulatory issues; proposed optimizations• Noted that as field and applications of DPS are expanding, the future status and trajectory of DBS research and use in clinical practice may change• Future of DBS therapy relies on continuing innovation and cooperation of stakeholders (patients, scientists, engineers, physicians, ethicists, administrators, policy makers)
<p>Human Performance Enhancement (HPE) Workshop</p> <p>(American Academy of Arts and Sciences, 2016)</p> <p>https://www.amacad.org/content/publications/pubContent.aspx?d=22348</p>	<p>Aims:</p> <ul style="list-style-type: none">• Review and analyze current state of research and policy discourse on HPE (i.e., ethical and legal framework of CED regulation)• Develop research agenda for multiyear study to enhance understanding of HPE and identify issues for further consideration <p>Outcomes:</p> <ul style="list-style-type: none">• Addressed lack of clarity in regulation of CEDs (i.e., are they medical devices?); suggested public database for post-market CED surveillance data to monitor safety, efficacy, and privacy; discussed CED usage by different age groups and possible overall consequences such as social inequities and skewed workplace expectations• Future work: (1) multidisciplinary roundtable discussions for CED safety and regulation measures, (2) consideration of possible long-term scenarios of impacts of neuromodulation at individual and societal levels





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<p>Cognitive Enhancement and Beyond: Recommendations from the Bioethics Commission</p> <p>(Allen & Strand, 2015)</p> <p>http://www.cell.com/trends/cognitive-sciences/fulltext/S1364-6613(15)00178-3</p>	<p>Aims:</p> <ul style="list-style-type: none"> • Address issue of media claims regarding the “epidemic” rise of CE despite lack of evidence • Broaden discussion of CE to include all forms of neural modification (“neural modifiers”) <p>Outcomes:</p> <ul style="list-style-type: none"> • Cautioned that neuroscience research is subject to media exaggeration • 5 Recommendations for Ethical Research and the Use of Neural Modifiers: (1) prioritize existing strategies to maintain and improve neural health, (2) prioritize treatment of neurological disorders, (3) study novel neural modifiers to augment/enhance neural function, (4) ensure equitable access to novel neural modifiers to augment/enhance neural function, (5) create guidance about the use of neural modifiers
<p>Non-Invasive Neuromodulation of the Central Nervous System: A Workshop</p> <p>(Forum on Neuroscience and Nervous System Disorders, 2015)</p> <p>http://www.nationalacademies.org/hmd/Activities/Research/NeuroForum/2015-MAR-2.aspx</p>	<p>Aims:</p> <ul style="list-style-type: none"> • Explore opportunities, challenges, and ethical questions surrounding the development, regulation, and reimbursement of non-invasive neuromodulation devices for both therapeutic and non-therapeutic uses with range of stakeholders (e.g., developers, researchers, clinicians, ethicists, regulators, payers) <p>Outcomes:</p> <ul style="list-style-type: none"> • Published report highlighting main points of presentation and discussion of workshop (https://www.ncbi.nlm.nih.gov/pubmed/26225405) • Topics included need for global collaboration and consultation to discuss device development regulations and reimbursement, to enhance understanding of safety and efficacy of non-invasive neuromodulation, and to clarify definitions of treatment vs. enhancement





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<p>Gray Matters: Integrative Approaches for Neuroscience, Ethics, and Society, Volume II</p> <p>(Presidential Commission for the Study of Bioethical Issues, 2015)</p> <p>http://bioethics.gov/sites/default/files/GrayMatter_V2_508.pdf</p>	<p>Aims:</p> <ul style="list-style-type: none"> • Broadly consider ethical and societal implications of neuroscience research and its applications • Focus on 3 pertinent topics: cognitive enhancement, consent capacity, and neuroscience and the legal system <p>Outcomes:</p> <ul style="list-style-type: none"> • 9 public meetings with diverse experts and stakeholders • 14 recommendations to guide ethical progress of neuroscience research and its applications with regards to: justice and stigmatization of groups and individuals; research to clarify persistent questions and fill gaps in current state of knowledge; accurate communication about ethical and practical implications and application of neuroscience research results; clarity around legal requirements and new guidance where needed; and need to support and advance innovative multidisciplinary research
<p>Gray Matters: Integrative Approaches for Neuroscience, Ethics, and Society, Volume I</p> <p>(Presidential Commission for the Study of Bioethical Issues, 2014)</p> <p>http://www.bioethics.gov/sites/default/files/Gray%20Matters%20Vol%201.pdf</p>	<p>Aims:</p> <ul style="list-style-type: none"> • Analyze why and how to achieve ethics integration early and explicitly throughout neuroscience research <p>Outcomes:</p> <ul style="list-style-type: none"> • 3 public meetings with diverse speakers including neuroscientists, philosophers, educators, ethicists, employees in the federal and private sectors involved in the BRAIN Initiative • 4 recommendations to facilitate successful integration of ethics and neuroscience research: (1) institutions and individuals should take steps to make explicit their plans and (2) provide sufficient resources for integrating ethics, (3) institutions and researchers should evaluate existing and innovative approaches to integrating ethics and neuroscience, (4) professionals with experience in ethics should be included in BRAIN Initiative-related advisory boards and funding review committees





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<p>Consensus on guidelines for stereotactic neurosurgery for psychiatric disorders</p> <p>(Nuttin et al., 2014)</p> <p>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4145431/</p>	<p>Aims:</p> <ul style="list-style-type: none">• Elaborate on existing guidelines for safe and ethical conduct of neurosurgical procedures for psychiatric disorders and adopt a pragmatic worldwide set of guidelines to enhance patient safety
	<p>Outcomes:</p> <ul style="list-style-type: none">• Stereotactic ablative procedures, while considered 'established' in some countries, still lack level I evidence• DBS in any brain target is still at an investigational stage• Researchers encouraged to design relevant randomized controlled trials, and noted that experienced multidisciplinary teams are required for safe and ethical conduct of any psychiatric neurosurgery
<p>Novel neurotechnologies: intervening in the brain</p> <p>(Nuffield Council on Bioethics, 2013)</p> <p>https://nuffieldbioethics.org/wp-content/uploads/2013/06/Novel_neurotechnologies_report_PDF_web_0.pdf</p>	<p>Aims:</p> <ul style="list-style-type: none">• Identify and consider the ethical, legal and social issues that arise from the use of novel neurotechnologies to intervene in the human brain in clinical practice and non-medical settings• Explore ethical issues from the communication and representation of neuroscientific research to intervene in the brain in the media and by researchers• Make recommendations for research, policy, governance, and public engagement
	<p>Outcomes:</p> <ul style="list-style-type: none">• 298-page report with cross-cutting themes: supporting innovation while protecting patients, providing access to novel therapies while safeguarding vulnerable individuals, maintaining trust about limits of current knowledge, collecting evidence while preserving scientific integrity, and treating brain disorders while monitoring impacts whole person• Recommended: responsible research governance, effective and proportionate oversight, high standards of care for patients, making existing evidence transparent and accessible, protecting interests of users in non-therapeutic contexts, responsible communication





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<p>Responding to requests from adult patients for neuroenhancements. Guidance of the Ethics, Law and Humanities Committee</p> <p>(Larriviere D, et al., 2013)</p> <p>https://www.aan.com/uploadedFiles/Website/Library_Assets/Documents/6.Public_Policy/1.Stay_Informed/2.Position_Statements/3.PDFs_of_all_Position_Statements/adult.pdf</p>	<p>Aims:</p> <ul style="list-style-type: none"> • Provide overview of ethical, legal, and social issues regarding request of pharmaceuticals for neuroenhancement by “normal adult patients” and how to respond to these requests <p>Outcomes:</p> <ul style="list-style-type: none"> • 14-item guide for requests for neuroenhancement medication • Suggested that neurologists should make the ultimate decision on whether to prescribe neuroenhancement medications in accordance with the laws in their states of practice • Careful consideration needed for future issue of neuroenhancement for normal children
<p>The Asilomar Survey: Stakeholders’ Opinions on Ethical Issues Related to Brain-Computer Interfacing</p> <p>(Nijboer, Clausen, Allison, & Hasellager, 2011)</p> <p>https://link.springer.com/article/10.1007/s12152-011-9132-6</p>	<p>Aims:</p> <ul style="list-style-type: none"> • Survey 145 BCI researchers on ethical issues important for BCIs and on issues such as terminology, criteria for BCI definition, expected marketability, and matters of urgency <p>Outcomes:</p> <ul style="list-style-type: none"> • Recommended actions: additional collaborative efforts like workshops, special sessions, web-based meetings, joint publications, and exploration of legal issues such as liability, privacy, and personal identity
<p>Brain Waves 1: Neuroscience, society, and policy</p> <p>(The Royal Society, 2011)</p> <p>https://royalsociety.org/~media/Royal_Society_Content/policy/publications/2011/4294974932.pdf</p>	<p>Aims:</p> <ul style="list-style-type: none"> • As a part of 4 ‘modules,’ to explore neuroscience results, implications, and potential benefits and risks • Provides a primer of current developments and highlights interesting issues and questions for science and policy <p>Outcomes:</p> <ul style="list-style-type: none"> • Reviewed state of development neuroimaging, neuropsychopharmacology, and neural interfaces • Recommended principles for social appraisal of neuroscience and neurotechnology: responsibility (independence from outside interests, accountability, transparency), precaution (justification and implications of applications), and engagement (access, public engagement)





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<p>Brain Waves 2: Neuroscience: implications for education and lifelong learning</p> <p>(The Royal Society, 2011)</p> <p>https://royalsociety.org/~media/Royal_Society_Content/policy/publications/2011/4294975733.pdf</p>	<p>Aims:</p> <ul style="list-style-type: none"> • Begin dialogue between research community, policy officials, and educational professionals to assess how educational policies can be enhanced with neuroscientific evidence <p>Outcomes:</p> <ul style="list-style-type: none"> • Recommendations: (1) neuroscience should be used as a tool in educational policy, (2) training and continued professional development should include a component of neuroscience relevant to educational issues, (3) neuroscience should inform adaptive learning technology, and (4) “knowledge exchange network” is required for neuroscientific progress
<p>Brain Waves 3: Neuroscience, conflict and security</p> <p>(The Royal Society, 2011)</p> <p>https://royalsociety.org/~media/Royal_Society_Content/policy/projects/brain-waves/2012-02-06-BW3.pdf</p>	<p>Aims:</p> <ul style="list-style-type: none"> • Examine potential military and law enforcement applications of neuroscience including resulting opportunities and risks <p>Outcomes:</p> <ul style="list-style-type: none"> • 10 recommendations for the scientific and international community and the UK government, emphasizing: • Neuroscientists should be taught to be aware of dual-use challenges from an early part of their training • Developing safe incapacitating chemical weapons is not feasible because of size/health/age of the target population, secondary injury, and requirement for medical aftercare • Countries should address definition and status of incapacitating chemical weapons
<p>Brain Waves 4: Neuroscience and the law</p> <p>(The Royal Society, 2011)</p> <p>https://royalsociety.org/~media/Royal_Society_Content/policy/projects/brain-waves/Brain-Waves-4.pdf</p>	<p>Aims:</p> <ul style="list-style-type: none"> • Discuss the important practical implications of recent neuroscience discoveries, including: risk assessment in probation and parole decisions, detecting deception, assessing memory, understanding pain, and Non-Accidental Head Injury <p>Outcomes:</p> <ul style="list-style-type: none"> • 5 recommendations across 3 broad topics: (1) bridging the gap between neuroscientific research and realities of legal system; (2) professionals in the legal system who might encounter neuroscience should understand its basic principles, limitations, and application challenges; (3) lack of research targeted to non-health sectors (i.e. education, law)





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<p>New Directions: The Ethics of Synthetic Biology and Emerging Technologies</p> <p>(Presidential Commission for the Study of Bioethical Issues, 2010)</p> <p>http://bioethics.gov/sites/default/files/PCSBI-Synthetic-Biology-Report-12.16.10_0.pdf</p>	<p>Aims:</p> <ul style="list-style-type: none"> • Examine implications of emerging science of synthetic biology • Offer recommendations to ensure benefits of this developing field within appropriate ethical boundaries <p>Outcomes:</p> <ul style="list-style-type: none"> • Outlined five principles relevant to assessing ethical considerations related to emerging technologies: (1) Public Beneficence, (2) Responsible Stewardship, (3) Intellectual Freedom and Responsibility, (4) Democratic Deliberation, (5) Justice and Fairness
<p>European Citizen's Assessment Report: Complete Results</p> <p>(Meeting of Minds; European Citizen's Deliberation on Brain Science, 2006)</p> <p>https://www.kbs-frb.be/en/Virtual-Library/2006/294903</p>	<p>Aims:</p> <ul style="list-style-type: none"> • Provide detailed overview of deliberation process (from themes to issues to final recommendations) by 126 citizens from nine European countries on complex matters of brain sciences, not reported in final report to Parliament <p>Outcomes:</p> <ul style="list-style-type: none"> • Highlighted the significance of and need for the general public's participation in shaping brain science policy • After 3 national meetings in each participating country and 2 European meetings, 37 recommendations on Brain Sciences finalized within 6 broad, cross-cutting themes: (1) regulation and control, (2) normalcy vs. diversity, (3) public information, (4) pressure from economic interests, (5) equal access to treatment, (6) freedom of choice
<p>Non-invasive research on human brain function</p> <p>(The Japanese Neuroscience Society, 2009)</p> <p>http://www.inss.org/en/guideline/rinri/</p>	<p>Aims:</p> <ul style="list-style-type: none"> • Revise 2002 guidelines on the implementation of non-invasive neurotechnology for human brain function research <p>Outcomes:</p> <ul style="list-style-type: none"> • Provided overview, effectiveness, risks, testing guidelines, and explanatory documents for human participants in research studies using the following neurotechnologies: MEG, TMS, PET, fMRI, NIRS, neuropsychological assessments, Brain Machine Interface, and research involving genome/genomic analysis • Addressed ethical issues directly in relation to subject participation in research studies by outlining approaches to informed consent, privacy protection, and precautions when presenting results at conferences and in academic journals

