Munich Center for Technology in Society
Technische Universität München

Developing Robust International Principles for Responsible Innovation:

Insights and Implications from Ongoing OECD Work on Neurotechnology and Society

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Agenda

1. **Responsible Innovation in International Settings**
2. **Towards OECD Principles for RI in Neurotechnology**
3. **Three Tensions and Draft Principles:**
   I. Unique concerns
   II. Multiple (soft) governance frameworks
   III. RI in business
4. **Conclusion and outlook**

1. Responsible Innovation in International Settings

- RI as an emerging imperative for STI policies
- Strong top-down institutionalization through EC
- Challenges in mainstreaming RRI across the EU
- Lead domain: Nanotechnology
- Towards a global RI framework?
  - Gaps in research and practice

RRI Tools
Fostering Responsible Research and Innovation

RRI
Responsible Research and Innovation
Shaping New Horizons
Responsible Research and Innovation in Europe and across the World
14-15|01|2016 | JDE 61, 62, 63
EESC | Jacques Delors Building
rue Belliard 99 | Brussels | 6th floor

2. Towards OECD Principles for RI in Neurotechnology

- The decade of the brain: hopes and concerns

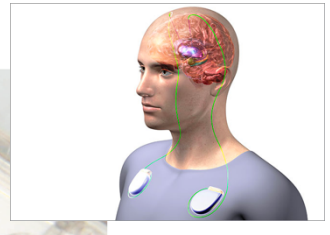
TECHNOLOGY

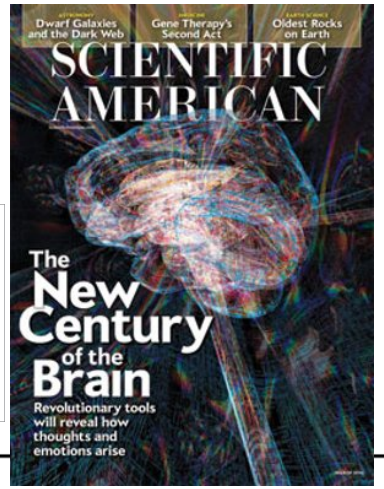
Hacking Your Brain: Neurotech Startups Aim To Treat Depression, Alzheimer's And Parkinson's Through Headsets

BY DAVID GILBERT ON 01/13/16 AT 9:26 AM

Simplified 3D brain organoids can be grown in a dish using human stem cells as the starting material.

The ethics of experimenting with human brain tissue





Ski jumpers rely on finely tuned skills to glide through the air and land safely.

NEUROSCIENCE

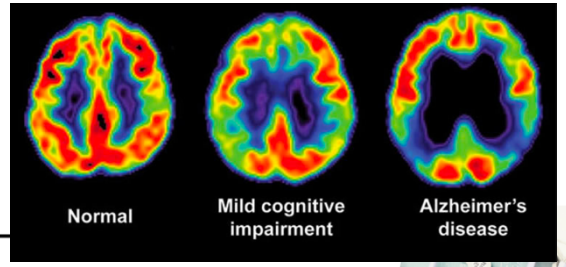
Performance boost paves way for 'brain doping'

Electrical stimulation seems to boost endurance in preliminary studies.

BY SARA REARDON

making it easier for them to hone their skills. Other research suggests that targeted brain

The USSA is working with Halo to judge the efficacy of a device that delivers electricity to the



Rewriting Life

The Entrepreneur with the $100 Million Plan to Link Brains to Computers

NATURE | NEWS

Worldwide brain-mapping project sparks excitement — and concern

HISTORY Two centuries of distorting publication metrics p.163 EXPLORATION On the trail of an ill-fated expedition to map the Arctic p.166 FUNDING African grant-giving bodies need more data to guide investments p.168 OBITUARY Vladimir Voevodsky, pioneer in algebraic geometry and computer proofs p.169

A man with a spinal-cord injury (right) prepares for a virtual cycle race in which competitors steer avatars using brain signals.

Four ethical priorities for neurotechnologies and AI

2.1 Neurotechnology spheres of use and implications

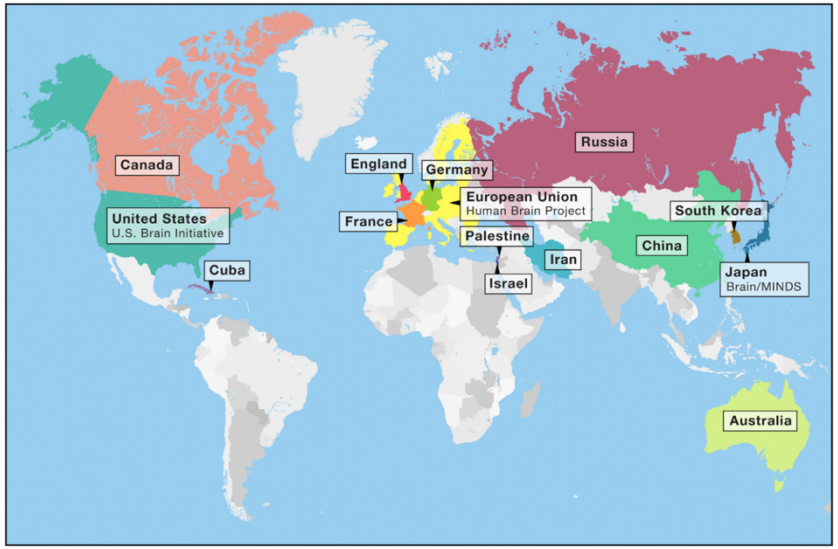
Neuroscience and technologies by primary function	
Reading brain	▪ Imaging ▪ Biomarkers ▪ modeling/mapping
Intervening/ Modulating the brain	▪ Pharmaceuticals ▪ Neurofeedback ▪ Transcranial Modulation ▪ Deep Brain Stimulation
Engineering the brain	▪ Brain-computer interface ▪ Neuroprosthetics
Derivative	▪ Artificial neural networks ▪ AI technologies

Spheres of use	
Clinical/medical	▪ Neurology/ ▪ Neurosurgery ▪ Psychiatry ▪ Rehabilitation ▪ Pain Medicine
Occupational	▪ Training ▪ Performance
Military	▪ Intelligence ▪ Weapons
Public (DTC; DiY)	▪ Educational ▪ Wellness/Lifestyle

Ethical, Legal Social Implications
▪ Informed consent ▪ Agency, identity, autonomy ▪ Stigma ▪ Prediction, prevention and therapeutic gaps ▪ Safety and efficacy ▪ Data / brain privacy ▪ Off-label use, misuse and coercive use ▪ Dual use ▪ Social and distributive justice and access ▪ Cognitive enhancement ▪ Optimization society ▪ Brain determinism ▪ Scientific evidence ▪ Neuroimages in the courtroom ▪ Neuromarketing ▪ Neuropolicies

2.2 An unprecedented momentum for NS/NT

- Worldwide rise of neurodegenerative diseases
- Rapid advancements and convergence (NBIC)
- Evolving markets for health and beyond
- Large scale national brain projects
- Collaboration and competition
- Calls for concerted action on ethical, legal, social implications



Yuste & Bargmann, *Cell*, 2017; OECD (BNCT) 2017.

2.3 BNCT Neurotechnology and Society Project

- Pool ideas, norms, and approaches for achieving more responsible innovation in neurotechnology through dialogue with stakeholders.
- Promote international deliberation, engagement, and transparency on the ethical, legal, societal, regulatory, and economic aspects upstream of neurotechnology development.
- Provide principles for responsible development, integration, and use of new and innovative neurotechnologies for health-related applications.

3. Three tensions

I. Unique concerns in neurotechnology *vs*. common concerns in emerging technologies

II. Multiple (soft) gov. frameworks *vs.* umbrella character of RI

III. RI in business *vs.* business in society

3.1 Unique Concerns in Neurotechnology Innovation

- **Brain privacy**: special provisions of brain data vs. other health data?
- **Treatment vs. enhancement:** where to differentiate?
- **Dual use, misuse, off-label use**: what is a medical / consumer device?

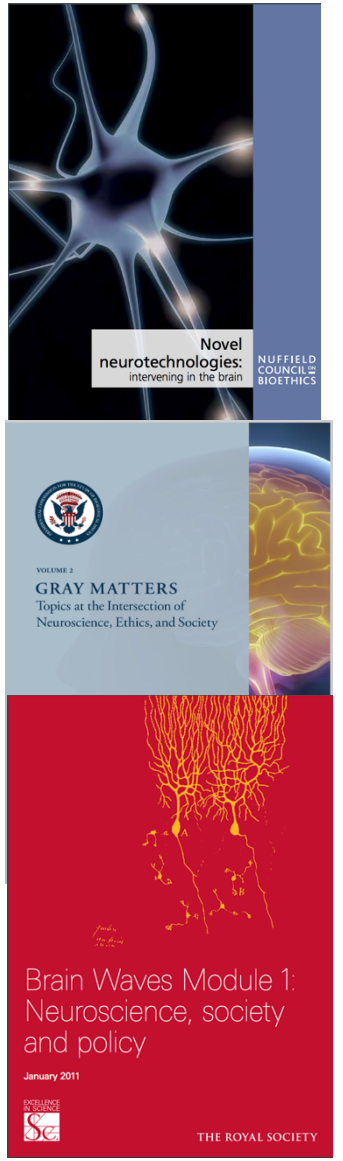
- ➢ Neurotech for health and wellbeing
- ➢ Special provisions on brain data
- ➢ Shared monitoring tools and oversight of risks
- ➢ adaptation of bioethics guidelines and procedures
- ➢ further research on short- and midterm ethical implications

3.2 Multiple (soft) Governance Frameworks

Brain Projects	U.S. BRAIN Initiative	E.U. Human Brain Project	Brain/MINDS Japan	South Korean Brain Initiative	Australian Brain Initiative	New Zealand Brain Research
Alignment mechanisms	▪ Ethical assessment in (voluntary) multi-council working group ▪ DARPA NeuroELSI Panel; ▪ Stakeholder approach	▪ Ethics and Society Subproject: Internal ethics mngmt and definition of Standard Operating Procedure ▪ Ethics advisory board; ▪ Foresight Lab and PE	▪ No direct mechanism/ ”in progress” ▪ authority within individual research institutions	▪ Neuro-ethics commit-tee (recently formed)	▪ Neuroethics committee ▪ Brain Dialogue Project (citizen juries, online discussions, participatory science)	▪ Ethical guidelines; ▪ Maori advisory board

3.2 Multiple (soft) Governance Frameworks

- Responsible stewardship of neurotechnology across sectors
- Institutional capacity to assess impacts on individuals AND society
- Democratic deliberation: oversight bodies and Public Engagement
- Inter- and transdisciplinary education, research and development



3.3 RI in Neurotechnology Business

- ELSI implications along the whole innovation process but particularly during commercialization
- Neurotechnology start-ups vs. MNEs and pharma
- PPPs and Open Science
- Business case: technology backlash, reputation
- Conceptual approach: RI in business or business in society?

Lumosity to Pay $2 Million to Settle FTC Deceptive Advertising Charges for Its “Brain Training” Program

Company Claimed Program Would Sharpen Performance in Everyday Life and Protect Against Cognitive Decline

3.3 RI in Neurotechnology Business

- Design and implementation of new and/or tested strategies for responsible innovation in business
- Transparent communication: early notification of risks in off-label use
- Clear disclosure of data use
- Cross-sectorial bodies for screening, reviewing and monitoring R&D projects and portfolios

4. Conclusion and Outlook

- Opportunities and challenges in mainstreaming RI
- Towards inclusive RI
  - Techno-scientific characteristics
  - Existing national governance frameworks
  - Needs and strategies of central stakeholders

➢ Neurotechnology Business consultation Shanghai, Sept 6-7 2018

➢ Deliberation across OECD countries