Developing Robust International Principles for Responsible Innovation:

Insights and Implications from Ongoing OECD Work on Neurotechnology and Society
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
2. Towards OECD Principles for RI in Neurotechnology

- The decade of the brain: hopes and concerns

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

Performing boost paves way for ‘brain doping’

Rewriting Life

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

Worldwide brain-mapping project sparks excitement — and concern

The ethics of experimenting with human brain tissue

Four ethical priorities for neurotechnologies and AI
2.1 Neurotechnology spheres of use and implications

<table>
<thead>
<tr>
<th>Neuroscience and technologies by primary function</th>
<th>Spheres of use</th>
<th>Ethical, Legal Social Implications</th>
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</thead>
<tbody>
<tr>
<td>Reading brain</td>
<td>Clinical/medical</td>
<td>▪ Informed consent</td>
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<td>▪ Imaging</td>
<td>▪ Neurology/Neurosurgery</td>
<td>▪ Agency, identity, autonomy</td>
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<td>▪ Biomarkers</td>
<td>▪ Neurosurgery</td>
<td>▪ Stigma</td>
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<td>▪ modeling/mapping</td>
<td>▪ Psychiatry</td>
<td>▪ Prediction, prevention and therapeutic gaps</td>
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<td>Intervening/Modulating the brain</td>
<td>▪ Rehabilitation</td>
<td>▪ Safety and efficacy</td>
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<td>▪ Pharmaceuticals</td>
<td>▪ Pain Medicine</td>
<td>▪ Data / brain privacy</td>
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<td>▪ Neurofeedback</td>
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<td>▪ Off-label use, misuse and coercive use</td>
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<td>▪ Transcranial Modulation</td>
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<td>▪ Dual use</td>
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<td>▪ Deep Brain Stimulation</td>
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<td>▪ Social and distributive justice and access</td>
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<td>Engineering the brain</td>
<td>Occupational</td>
<td>▪ Cognitive enhancement</td>
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<td>▪ Brain-computer interface</td>
<td>▪ Training</td>
<td>▪ Optimization society</td>
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<td>▪ Neuroprosthetics</td>
<td>▪ Performance</td>
<td>▪ Brain determinism</td>
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<tr>
<td>Derivative</td>
<td>Military</td>
<td>▪ Scientific evidence</td>
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<td>▪ Artificial neural networks</td>
<td>▪ Intelligence</td>
<td>▪ Neuroimages in the courtroom</td>
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<td>▪ AI technologies</td>
<td>▪ Weapons</td>
<td>▪ Neuromarketing</td>
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<td>Public (DTC; DiY)</td>
<td>▪ Neuropolicies</td>
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<td>▪ Educational</td>
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<td>▪ Wellness/Lifestyle</td>
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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

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

<table>
<thead>
<tr>
<th>Brain Projects</th>
<th>U.S. BRAIN Initiative</th>
<th>E.U. Human Brain Project</th>
<th>Brain/MINDS Japan</th>
<th>South Korean Brain Initiative</th>
<th>Australian Brain Initiative</th>
<th>New Zealand Brain Research</th>
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<tr>
<td><strong>Alignment mechanisms</strong></td>
<td>▪ Ethical assessment in (voluntary) multi-council working group</td>
<td>▪ Ethics and Society Subproject: Internal ethics mgmt and definition of Standard Operating Procedure</td>
<td>▪ No direct mechanism/“in progress”</td>
<td>▪ Neuro-ethics committee (recently formed)</td>
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<td>▪ Ethical guidelines; Maori advisory board</td>
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<td>▪ DARPA NeuroELSI Panel;</td>
<td>▪ Ethics advisory board;</td>
<td>▪ authority within individual research institutions</td>
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<td></td>
<td>▪ Stakeholder approach</td>
<td>▪ Foresight Lab and PE</td>
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- **U.S. BRAIN Initiative**
  - Ethical assessment in (voluntary) multi-council working group
  - DARPA NeuroELSI Panel;
  - Stakeholder approach

- **E.U. Human Brain Project**
  - Ethics and Society Subproject: Internal ethics mgmt and definition of Standard Operating Procedure
  - Ethics advisory board;
  - Foresight Lab and PE

- **Brain/MINDS Japan**
  - No direct mechanism/“in progress”
  - authority within individual research institutions

- **South Korean Brain Initiative**
  - Neuro-ethics committee (recently formed)

- **Australian Brain Initiative**
  - Neuroethics committee
  - Brain Dialogue Project (citizen juries, online discussions, participatory science)

- **New Zealand Brain Research**
  - 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?
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