Towards Responsible Innovation in Neurotechnology:

A comprehensive framework and evaluation tool

by
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Abstract

Neurotechnology is a rapidly advancing field that enhances our understanding of the brain, consciousness, and complex cognitive functions. While it holds great potential for improving daily life of people with disabilities and reshaping concepts of human-technology integration, it also poses significant risks. Improper use of neurotechnology can harm individuals, raising concerns about identity, autonomy, privacy, and safety. The differentiating line between medical and non-medical neurotechnology is blurred, with the term ‘neurotechnology’ itself remaining loosely defined. The policy initiatives surrounding neurotechnology are still evolving and there are gaps in translating the existing policies into actions or evaluating the progress of the actions in a neurotechnology enterprise.

This major research project explores the policy landscape of neurotechnology through the lens of responsive innovation. The design outcome of this project is a comprehensive framework and evaluation tool for responsible innovation in neurotechnology. The tool is designed for regulatory bodies to evaluate the status or progress of neurotechnology enterprises in responsible innovation. The Responsible Neurotechnology Framework (RNF) has four key components: governance, user, data, and technology. This is foundational in guiding stakeholders to the key areas to focus during the neurotechnology life cycle. The accompanying Responsible Neurotechnology Evaluation Tool (RNET) outlines the actions that are evidence of responsible innovation in the organizational practices of a neurotechnology enterprise. RNET serves as a tool for regulatory bodies to assess the status of responsible innovation within an enterprise and to monitor its progress over time against the four key components of the framework. By supporting both point-in-time assessment and ongoing progress monitoring, the design artifact helps ensure that neurotechnology innovations align with ethical standards, regulatory expectations, and societal needs.

This project demonstrates how inclusive design can inform the governance of emerging technologies, ensuring that innovation is not only accessible but also ethically grounded, user-centered, and socially accountable.

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Dedication

To my husband Jeemon and our son Yohan

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Chapter 1 – Introduction

Introduction to neurotechnology

From ancient practices such as trepanation to modern imaging and stimulation technologies, humanity has continually sought to understand and treat brain disorders (Kandel et. al., 2000). The use of technical devices to support diagnosis, therapy, and rehabilitation for brain disorders has a long-standing history in medicine. Canadian Brain Research Strategy (n.d.) reports 1 in 5 (7.5 million) Canadians live with a brain condition. This report also says that our brains shape our memories, passions, and societies. So, the implications extend past individual well-being to impact families, societies, and humanity when we are challenged by a neurological disorder, brain injury, mental illness and/or addiction.

Neurotechnology is a fast-expanding field dedicated to understanding the brain and creating technologies that interact with it (UNESCO, n.d.). Organization for Economic Co-operation and Development (OECD)'s Recommendation of the Council on Responsible Innovation in Neurotechnology (2025) defines neurotechnology as devices and procedures used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of the neural systems of natural persons. It includes a broad and heterogeneous spectrum of methods, systems, and instruments that establish a pathway to the human brain through which neural activity can be recorded and/or altered (Ienca, 2021). The Institute of Electrical and Electronic Engineers (2022) has described neurotechnology as the 'next technology frontier,' highlighting both its disruptive potential and the urgency of addressing its broader implications. Globally, approximately one in eight people live with a mental or neurological disorder (Institute for Health Metrics and Evaluation, 2019), underscoring both the promise and pressure surrounding the development of neurotechnology.

From medications that improve daily functioning to imaging that reshapes our understanding of consciousness, neurotechnology is poised to redefine our understanding of the human mind. Its applications appear limitless: in education, it could personalize learning experiences; in commerce, it might align consumers' desires with

available products; and in computing, thought-to-text systems and brain-assisted virtual and augmented reality experiences may revolutionize interaction and entertainment. Neurotechnology stands as a transformative force, capable of enhancing life in unprecedented ways.

Ienca and Andorno (2017) state that while the excitement surrounding neurotechnology should be embraced, its limitations, along with concerns about governance, regulation, and potential risks to patients, must also be recognized. They emphasize that many neurotechnology innovations are still in the research phase, and the path to clinical use is complex, requiring collaboration to address technological, clinical, and ethical challenges. Strict regulations are necessary to ensure accurate data, prevent bias, and avoid discrimination. Since brain activity is essential to cognitive, emotional, and mental states and is closely tied to personal identity and privacy, neurotechnology's ability to record or alter it presents significant ethical and legal concerns. Therefore, proactive discussions and the implementation of ethical and regulatory frameworks are crucial to safeguarding against misuse. The domain of neurotechnology is at the intersection of neuroscience, engineering, and artificial intelligence, that encompasses the development and application of tools and techniques designed to interact with the nervous system. While neurotechnology offer novel ways to diagnose, treat, and manage such conditions, it also challenge existing policies for health, medical devices, drugs and artificial intelligence.

Need for responsible innovation in neurotechnology

Globally, approximately one in eight people live with a mental or neurological disorder (Institute for Health Metrics and Evaluation, 2019), underscoring both the promise and pressure surrounding the development of neurotechnology. There is an urgent need for a shared understanding of the interactions between neurotechnology development and policy development especially as questions about societal impact, legal boundaries, and technological governance come to the fore. Without guidance rooted in responsibility, technologies could exacerbate inequalities, infringe on rights, or be misused in ways that erode public trust. A forward-looking, principle-based approach to responsible innovation is therefore not just desirable; it is urgent.

“Neurotechnology has the potential to solve many health issues, but it could also threaten human rights, freedom of thought and privacy….There can be no neurodata without neurorights.”

- *Audrey Azoulay, UNESCO Director General*

Despite the need, creating effective policies for neurotechnology is challenging because the field is new and combines many areas, such as neuroscience, data science, artificial intelligence, medicine, and consumer technology, each with its own rules and regulations. This makes it hard to create unified policies. There are issues like limited expertise in some areas, unclear terms, different regulations across regions, and uncertainty about future risks. Even after policies are created, it is hard to put them into action due to limited resources, lack of agreement among stakeholders, and unclear ways to enforce them. These problems prevent policies from keeping up with the fast pace of innovation. The approval process for neurotech medical devices is slow and costly, and monitoring after products are released is inconsistent. Current policies are often reactive and struggle to handle new uses of neurotechnology or address misuse (Stieglitz, 2021).

The commercialization of neurotechnology and the use of neural data in areas such as marketing and surveillance have already begun, raising ethical and legal red flags. For some, the sentiment is that the horse is already out of the barn, and we are now reacting to consequences that should have been anticipated through more proactive policymaking. Moreover, questions such as who qualifies to implant neurotechnological devices or how Do-It-Yourself (DIY) neurotech like kits or devices people use outside formal medical settings is regulated point to broader accountability gaps (Farhany, 2023). OECD working paper on responsible innovation in neurotechnology enterprises (2019) identified some challenges in neurotechnology enterprises such as lack of established pathways such as deliberative exercises and ethics boards, lack of time and resources to commit organizational capital for responsible innovation, skew in incentive structures due to investor-driven demands that limit responsible innovation efforts. UNESCO’s report on ethics in neurotechnology (2023) states that companies can use neural data obtained from non-invasive neurotech devices for marketing purposes. By detecting signals related to our preferences and dislikes, these companies can influence

customer's behavior for profit maximization. This raises alarming questions about surveillance, marketing tactics, and political influence on our most private thoughts and emotions, ultimately threatening our democracies and the foundations of society. UNESCO (n.d.) report highlights a 700% increase in investments in neurotech companies globally between 2014 and 2021, bringing the total investment to USD 33.2 billion. Of the 1,400 neurotech companies worldwide, 50% are based in the USA, and 35% are in Europe and the UK. The growth of the sector is further reflected in the Harvard Business Review (2023), which reports that the neurotechnology market is expanding at a compound annual growth rate of 12% and is expected to reach $21 billion by 2026.

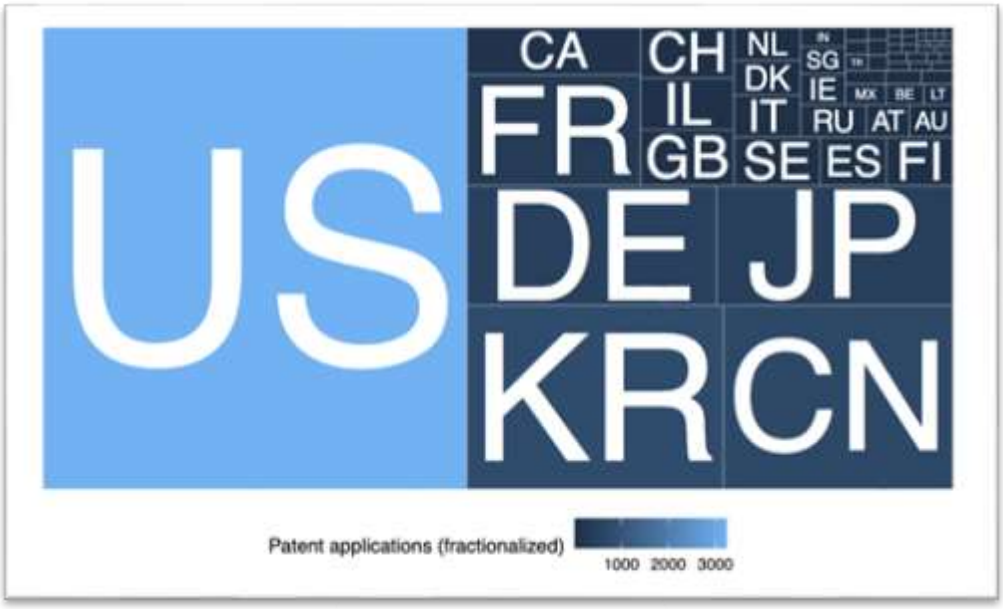

Figure 1: Patent applicants in neurotechnology by country (2000-2020). Data from the European Patent Office's Worldwide Patent Statistical Database (PATSTAT) and the UNESDOC Digital Library

The rapid advancement of neurotechnology has outpaced the development of corresponding policies, creating significant governance challenges. This misalignment is compounded by the Collingridge Dilemma, which highlights the difficulty in regulating emerging technologies due to limited early knowledge and the entrenchment of systems as technologies mature (Demos Helsinki, 2022). Additionally, the Precautionary Principle suggests that in situations of scientific uncertainty, preventive measures should be taken to avoid potential harm, even if full evidence is lacking (Canadian Biotechnology Action Network, n.d.). Together, these underscore the necessity for

proactive and adaptive policy mechanisms to address the ethical, legal, and societal implications of neurotechnology.

Without robust policy implementation mechanisms existing policies risk becoming symbolic rather than operational. Even when guidelines, principles policies, and regulations exist, translating them into concrete actions presents significant hurdles in neurotechnology enterprises (OECD, 2019). Ambiguity in policy language, lack of actionable roadmaps, and insufficient stakeholder involvement can all lead to implementation gaps. These challenges highlight the need for a more practical, adaptable framework that bridges the gap between policy intent and operational reality. Given the rapid advancement in the field, there is a critical need for an evaluation mechanism to understand and assess where neurotechnology enterprises stand in adopting responsible innovation practices.

Problem statement

There is a lack of practical mechanisms for regulatory bodies to assess and monitor how neurotechnology enterprises are implementing responsible innovation practices. While high-level principles and recommendations exist, they are difficult to translate into actionable organizational practices, creating a gap in oversight, evaluation, and continuous improvement. Without actionable tools to evaluate organizational practices, there is a risk that inclusion efforts may be superficial or harmful, leading to unintended consequences, exploitation, or erosion of trust. This limits the ability of regulators to promote accountability, guide continuous improvement, and safeguard the well-being of those most affected by neurotechnology.

Project scope

This research is focused on the development of a comprehensive framework for responsible innovation in neurotechnology, accompanied by an evaluation tool designed to assess the status and progress of responsible innovation in neurotechnology enterprises. The study takes a broad view of the global neurotechnology landscape. The scope is not confined to any specific type or application but extends across the full spectrum of neurotechnology, including both medical and non-medical products. The

framework and evaluation tool are intended to support regulatory bodies in assessing the level of responsible innovation in neurotechnology. This study is positioned within the design research context, with emphasis on the dimensions of inclusive design - recognizing diversity and uniqueness, inclusive process and tools, and broader beneficial impact (Inclusive Design Research Centre [IDRC], n.d.).

Design process

The design process for this project is grounded in the concept of the virtuous tornado, a model from inclusive design that illustrates how iterative co-design leads to increasingly ethical, inclusive, and impactful innovation. Rather than progressing linearly, the process follows a dynamic spiral where each cycle—comprising development, implementation, evaluation, and refinement—is informed by the injection of diverse user needs and characteristics. This iterative approach ensures that voices typically excluded from mainstream innovation, especially those at the margins, shape the direction and outcome of the design. As the design evolves through successive cycles, it results in solutions that are not only more inclusive, but also more adaptable, resilient, accessible, and innovative. This process reflects the commitment to responsible inclusion, where the design process actively avoids harm and fosters equity across the neurotechnology landscape.

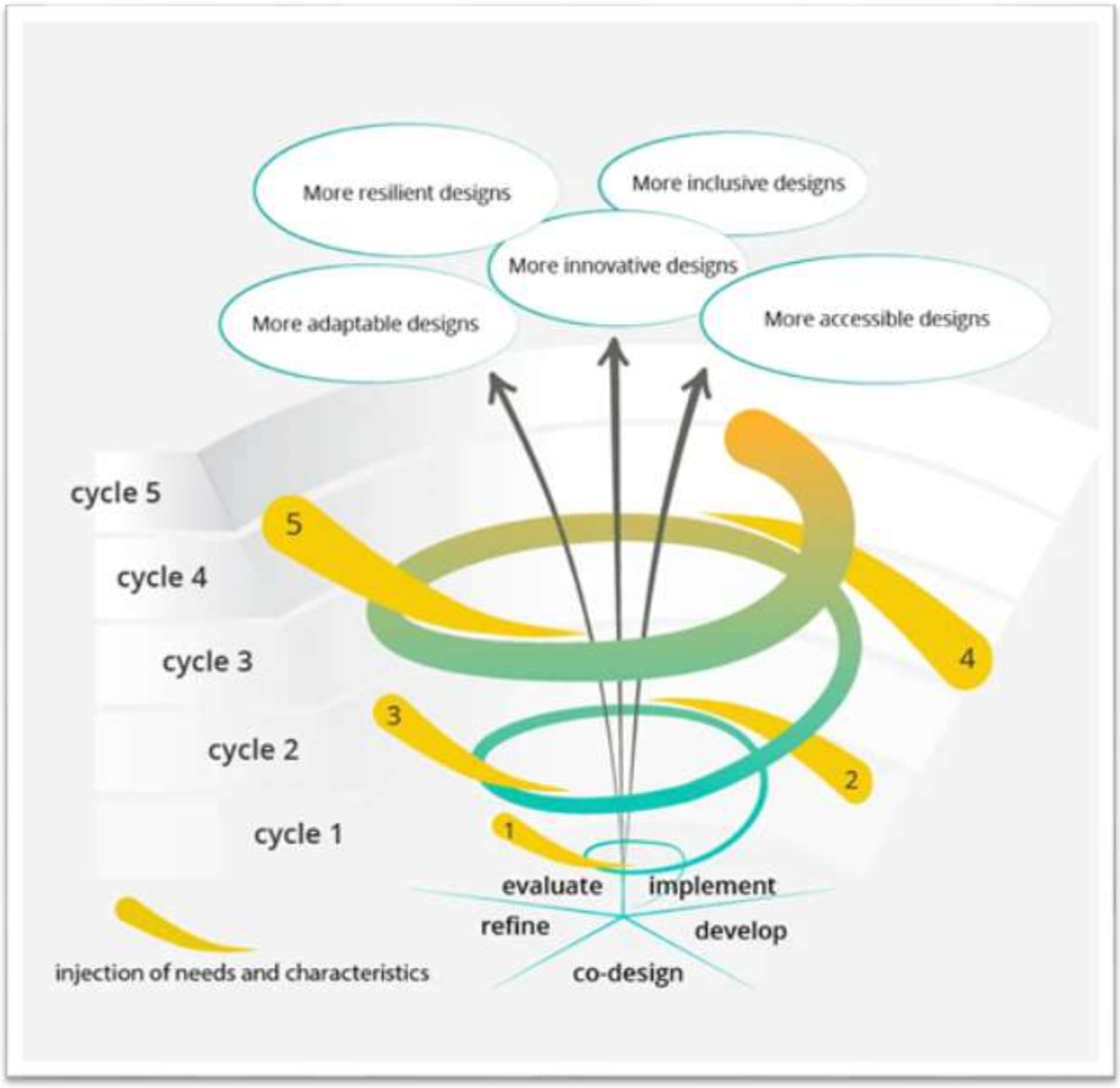

Figure 2: The Virtuous Tornado: A model of iterative inclusive design showing how co-design and the continuous integration of diverse needs produce increasingly inclusive and resilient outcomes over time. (Source: Inclusive Design Research Centre, OCAD University

This project adopts co-design as a foundational principle across various phases of the process. In the first phase, the project explored the policy landscape, emerging trends, and stakeholder input related to responsible neurotechnology innovation through environmental scan and expert interviews. During the second phase, insights were

synthesized to frame the problem space, leading to the development of a conceptual framework outlining key organizational dimensions essential for responsible innovation. In the third phase, this framework informed the design of a prototype evaluation tool, which was iteratively refined based on feedback from subject matter experts. In the fourth phase, the final the evaluation tool was produced, accompanied by recommendations for continuous improvement to keep pace with the evolving neurotechnology landscape.

Methodology

In the first phase, an environmental scan was conducted to map the current policy landscape of responsible neurotechnology innovation. Semi-structured conversations with subject matter experts provided additional insights into gaps and priorities. During the second phase, insights were synthesized to frame the problem space, leading to the development of a conceptual framework outlining key organizational dimensions essential for responsible innovation. Mind mapping techniques were used to visually organize findings from the first phase, helping to identify connections and emerging themes. These mind maps informed a thematic analysis that led to the identification of four key organizational dimensions forming the foundation of the framework. The thrid phase employed iterative prototyping, incorporating expert feedback cycles to refine both the framework and a practical evaluation tool designed to align with regulatory needs. In the fourth phase, the final artifacts were validated against the research objectives, and recommendations for continuous improvement were proposed to ensure the tool remains adaptable to evolving technological and policy landscapes.

Design outcome

The design outcome of this project is a comprehensive framework composed of the key organizational dimensions of responsible innovation and an accompanying evaluation tool that enables regulatory bodies assess and monitor responsible innovation practices in neurotechnology enterprises across key organizational dimensions.

The design artifact consists of two integrated components:

- Responsible Neurotechnology Framework (RNF) and
- Responsible Neurotechnology Evaluation Tool (RNET)

Together, these provide a practical and adaptable structure for responsible innovation and an actionable mechanism for policy implementation.

To conclude, this project achieves the goal of addressing the challenges associated with translating high-level policy principles and guidelines into tangible, actionable policy actions. Ultimately, the design outcome seeks to bridge the gap between policy intent and operational implementation, ensuring that responsible innovation is effectively realized in the neurotechnology field.

Chapter 2 – Neurotechnology policy landscape

Environmental scan of neurotechnology policy landscape

The global rise in brain research and neurotech innovation spanning clinical therapies, brain-computer interfaces, neural monitoring devices, and cognitive enhancement tools has outpaced the development of adequate policy or regulatory safeguards. Major scientific initiatives such as the United States' BRAIN Initiative and the European Union's Human Brain Project, both launched in 2013, alongside Japan's Brain/MINDS, China's Brain Project, and Canada's Brain Research Initiative, highlight a global momentum toward unlocking the brain's potential. Simultaneously, commercial interest in neurotechnology is surging, with increasing investment in consumer neurotech and mental health applications. International organizations like UNESCO and the OECD have issued critical recommendations to guide innovation in line with human rights, equity, and safety, while countries such as Chile, through its constitutional amendment on neuroprotection, and the U.S., with emerging bills on neurodata, are beginning to respond through targeted regulatory efforts. Despite these developments, the policy landscape remains fragmented and reactive, often ill-equipped to address the complex challenges posed by neural data, cognitive liberty, and algorithmic influence. Building a strong, inclusive, and anticipatory policy framework is therefore essential to ensure that neurotechnology evolves responsibly and equitably.

Neurotechnology-relevant policy initiatives

The environmental scan focused on identifying policy initiatives that, while not specific to neurotechnology, hold significant relevance for its development, regulation, and ethical oversight. These include broader frameworks related to data protection, medical device regulation, artificial intelligence governance, research ethics, and human rights. Such policies provide foundational principles and regulatory expectations that influence how neurotechnology is developed, deployed, and evaluated across different jurisdictions. By examining these cross-sectoral initiatives, the scan aimed to understand the existing policy environment that neurotechnology enterprises must

navigate and to identify gaps where neurotechnology-specific considerations are not yet fully addressed.

Policy initiatives	***Jurisdiction***	***Legally binding***	***Relevance to neurotech***	***Focus area***	***Applies to***
HIPAA (1996)	United States	Yes	High	Privacy	Clinical
Oviedo Convention (1999)	Regional (Europe)	Yes	Medium	Informed Consent, Privacy	Clinical
PIPEDA (2004)	Canada	Yes	Medium	Privacy	Non-clinical
UNESCO Bioethics Declaration (2005)	Global	No	Medium	Informed Consent, Equity	Both
Principles of Biomedical Ethics (2009)	Global	No	High	Ethics, Autonomy, Beneficence	Clinical
Responsible Innovation Framework (2013)	Global	No	High	Innovation, Inclusion, Ethics	Both
GDPR (2016)	Regional (EU)	Yes	High	Privacy, Data Protection	Both
TCPS 2 (2018)	Canada	No	High	Informed Consent, Research Ethics	Clinical
IEEE Code of Ethics (2020)	Global	No	Medium	Engineering Ethics, Safety	Both
EU MDR (2017)	Regional (EU)	Yes	High	Medical Device Safety	Clinical
WHO AI Ethics (2021)	Global	No	High	AI Ethics, Safety, Equity	Both
EU AI Act (2024)	Regional (EU)	Yes	High	AI Risk Management, Innovation	Both
Canada's Accessible and Equitable AI Systems – Draft Standard (2025)	Canada	No (Draft)	High	Accessibility, Equity	Both

Figure 3: Policy Landscape Matrix of neurotechnology-relevant initiatives generated by the author through comparison of policy initiatives

This environmental scan of neurotechnology-relevant policy initiatives highlights that while several policy initiatives - spanning privacy, ethics, informed consent, medical device regulation, and artificial intelligence governance - are highly relevant to neurotechnology, most were not originally designed with neurotechnology-specific challenges in mind. Although many frameworks provide strong foundations for responsible innovation, gaps remain in translating these broad principles into actionable requirements tailored to the unique ethical, legal, and societal complexities of neurotechnology. This underscores the need for sector-specific mechanisms to bridge

the gap between existing regulatory structures and the emerging realities of neurotechnology development and deployment.

Neurotechnology-specific policy initiatives

The environmental scan also examined neurotechnology-specific policy initiatives that directly address the unique risks, ethical considerations, and regulatory challenges associated with this emerging field. These targeted efforts provide critical insights into how governments and organizations are beginning to tailor legal and ethical frameworks specifically for neurotechnology development and deployment.

initiatives	***Jurisdiction***	***Legally Binding***	***Focus Area***	***Applies to***
Neuroethics Guiding Principles for the NIH BRAIN Initiative (2018)	United States	No	Safety, Privacy, Autonomy, Public Engagement	Clinical
NeuroRights Initiative Columbia University (2019)	Global	No	Mental Privacy, Identity, Free Will	Both
OECD Recommendations on Responsible Neurotech Innovation (2019)	Global	No	Responsible Innovation, Human Rights, Privacy	Both
FDA guidelines for Brain Computer Interfaces (2018)	United States	Yes	Safety, Efficacy, Regulatory Pathways	Clinical
Chile - Neuro-Rights Legislation (2021)	Chile	Yes	Mental Privacy, Personal Identity, Free Will	Both
Minnesota House File 1904 (2023)	United States (Minnesota)	No	Neurodata Rights, Privacy, Consent	Both
Mexico's General Law on Neurorights and Neurotechnology (2024)	Mexico	Yes	Neurodata, Informed Consent, Cyberneurosecurity	Both
Colorado's Neural Data Privacy Law (H.B. 24-1058, 2024)	United States (Colorado)	Yes	Neural Data Privacy, Consumer Protection	Non-clinical
Japan's Neurotech Guidebook for Responsible Development (2024)	Japan	No	Safety, Legal Compliance, Scientific Validation	Both
UNESCO's Recommendation on the Ethics of Neurotechnology (2024)	Global	No	Mental Privacy, Cognitive Liberty, Informed Consent	Both
California Consumer Privacy Act Amendment (2025)	United States (California)	Yes	Neural Data, Privacy, Consumer Protection	Non-clinical

Figure 4: Policy Landscape Matrix of neurotechnology-specific initiatives generated by the author through comparison of policy initiatives

This scan of neurotechnology-specific policy initiatives reveals a growing global recognition of the unique ethical, legal, and societal challenges posed by advancements in neurotechnology. While some jurisdictions have begun enacting legally binding protections, such as Chile's Neuro-Rights Law and emerging neural data privacy laws in the United States and Mexico, many frameworks remain non-binding and principle-based. Collectively, these initiatives emphasize critical issues such as mental privacy, cognitive liberty, informed consent, and safety, but variations in scope, enforcement, and application highlight the need for more harmonized and actionable regulatory approaches as the neurotechnology landscape continues to evolve.

Insights from environmental scan

Across both landscape matrices, key recurring focus areas include Privacy, Safety, Informed Consent, Human Rights, Responsible Innovation, Mental Privacy, AI Ethics, and Regulatory Pathways - showing strong intersections between traditional regulatory concerns and emerging neurotechnology-specific needs.

The environmental scan also revealed several critical gaps in the current policy landscape relevant to responsible neurotechnology innovation. A major insight was the lack of a unified global policy framework, leading to inconsistencies across jurisdictions. There is also significant difficulty in translating high-level principles into concrete organizational practices, leaving enterprises without clear operational guidance. Furthermore, policies often lack sufficient directives for user engagement in product development decisions, limiting stakeholder participation. Ambiguity persists around the protection of neural data, with unclear standards for privacy and security. Lastly, product safety requirements specific to neurotechnology remain inadequately defined, creating uncertainty in regulatory expectations.

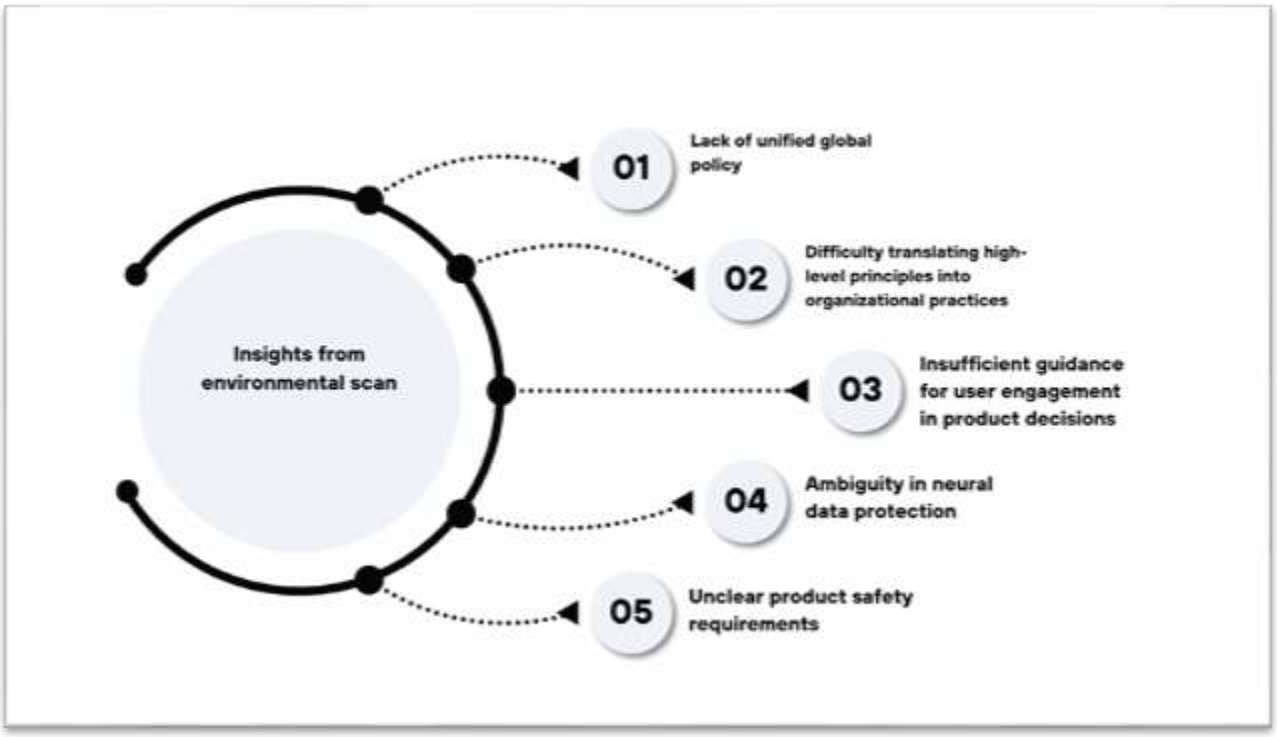

Figure 5: Insights from environmental scan

Stakeholder Engagement

To guide the development of a responsible neurotechnology innovation framework, a targeted group of stakeholders was identified. Experts in neurotechnology, neuroethics, policy, privacy, and safety were selected based on their current roles in government agencies, industry, and academia. Experts were chosen for this research because they possess the specialized knowledge and experience necessary to address the complex ethical, legal, and technical challenges associated with neurotechnology innovation. Their insights provide a comprehensive understanding of regulatory frameworks, technological advancements, and emerging risks, which are essential for shaping policies and guidelines. While user input is crucial in further developments after this research, the initial foundational research requires expert perspectives to ensure that responsible innovation is grounded in evidence-based practices and aligned with current regulatory standards.

Expert interviews

The primary methodology employed to gather insights was expert interviews, conducted remotely using Zoom or MS Teams platforms. Each interview lasted approximately 30 minutes and involved a purposive sample of 8 experts in neuroethics, privacy, safety, health policy, and neuroscience research. The goal was to gather factual information regarding current neurotechnology-related policy initiatives. While the interviews allowed for open dialogue, they were guided by the structured questions to ensure consistency and focus during the session.

The questions in the first phase session were as follows:

1. What current policy initiatives related to neurotechnology are active or under development?
2. Which national or international regulations must organizations developing neurotechnology comply with?
3. Is there an existing method or tool used by regulatory bodies to evaluate where a neurotechnology initiative stands in terms of responsible innovation?
4. Do you have access to sufficient data and evidence to inform the development and implementation of neurotechnology-related policies?
5. What are the current key priorities or focus areas in relation to the development, regulation, or oversight of neurotechnology?

Necessary accommodations were made to ensure accessibility for all experts. Alternative methods, such as surveys and focus groups, were considered, but the one-on-one interview format was deemed most effective for collecting specific, fact-based information on existing policy initiatives. This approach enabled a focused and efficient gathering of relevant data on the current state of neurotechnology policies.

Insights from stakeholder engagement

Insights from expert interviews emphasized several pressing needs for advancing responsible neurotechnology innovation. Participants noted that international best practices and global recommendations are still evolving, leading to a dynamic but uncertain regulatory environment. There is a lack of clear frameworks that translate soft laws and ethical guidelines into enforceable regulations, particularly for non-medical

neurotechnology products. Stakeholders highlighted the absence of tools to map where companies currently stand in terms of responsibility, making evaluation and oversight challenging. They also stressed the need for more guidance and up-to-date information to help align policy with the rapid pace of technological advancement. Finally, experts emphasized that further stakeholder input is critical to developing balanced, inclusive, and future-ready regulatory frameworks.

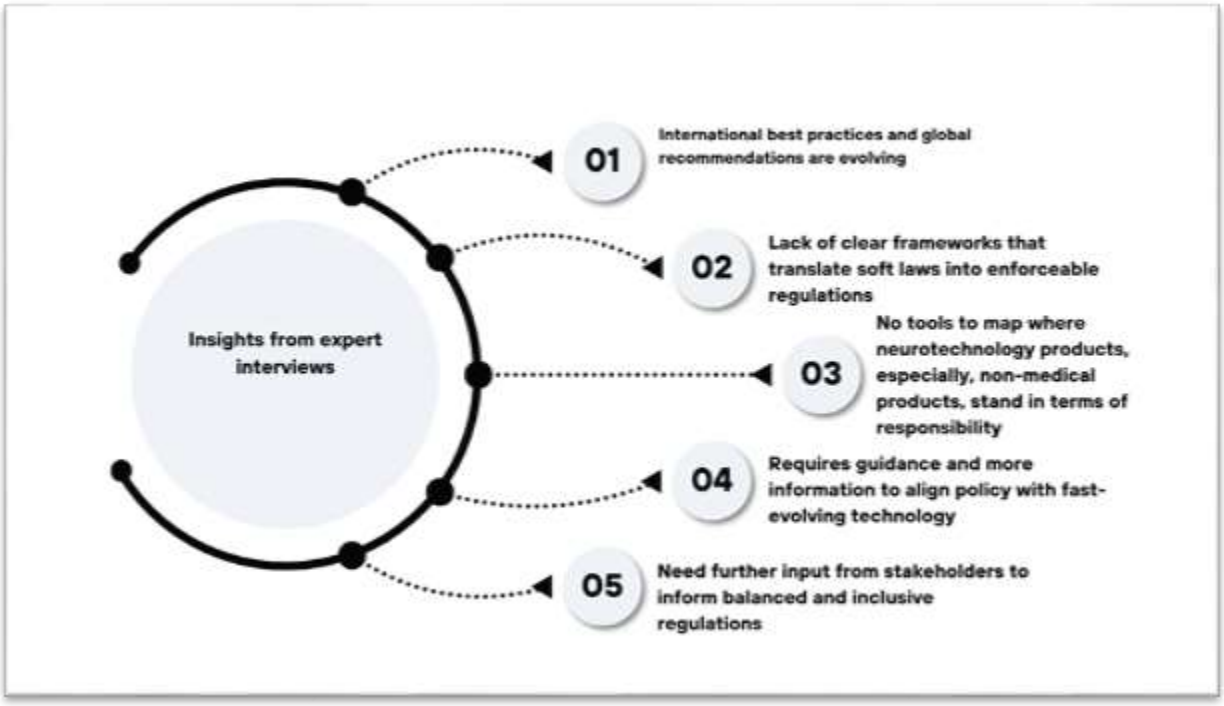

Figure 6: Insights from stakeholder engagement

User persona

In this research, the user persona represents a regulatory official responsible for evaluating neurotechnology products and ensuring alignment with ethical, legal, and policy standards. The persona was developed based on insights from policy documents and expert conversations, and it guided the design of the evaluation tool to meet the real-world needs of regulators overseeing responsible innovation.

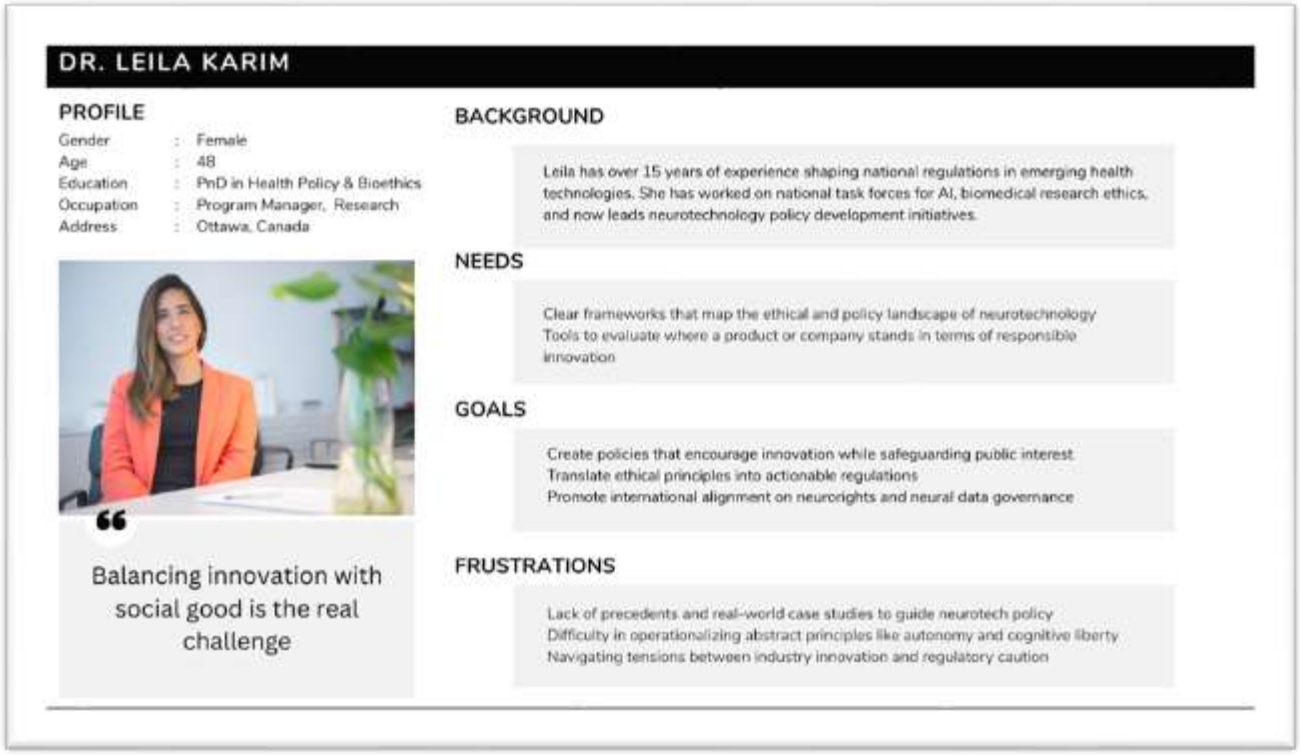

Figure 7: User persona

Key Insights

A critical priority identified during the first phase, emerging consistently from both the environmental scan of the neurotechnology policy landscape and stakeholder engagement, was the difficulty in translating high-level principles of responsible innovation into concrete organizational practices. While numerous international guidelines and ethical frameworks exist, such as those from the OECD and UNESCO, there is a notable gap in how these principles are operationalized within neurotechnology enterprises. Stakeholders emphasized the lack of practical tools to assess whether and how organizations are aligning with these principles in day-to-day operations. This highlighted an urgent need for a structured evaluation mechanism that can help regulatory bodies and organizations understand their current positioning and progress in implementing responsible innovation.

To conclude, the first phase has provided a deeper understanding of the problem where the insights from stakeholder engagement resonates well with the insights neurotechnology policy landscape scan. Through the creation of user persona, valuable insights into the diverse needs, motivations, and pain points of the policy makers,

implementers or regulatory bodies involved is detailed. This foundational knowledge serves as the basis for developing a responsible neurotechnology framework and tool that meets user needs. Moving forward, these insights guide the second phase, where the researcher prioritize the key issues and refine the scope of the framework to address the most critical priorities identified during this phase.

Chapter 3 – Responsible Neurotechnology Framework (RNF)

The second phase focuses on making sense of the insights gathered during the first phase to clearly articulate the core design challenge. This stage involved organizing and analyzing data from the environmental scan and expert interviews to identify key patterns, needs, and opportunity areas. The outcome of this phase was the development of a conceptual framework and a refined problem statement to guide the design of the evaluation tool.

Synthesizing insights from environmental scan and expert interview

The synthesis of insights from the first phase involved a structured process of organizing findings from the environmental scan and expert interviews to identify patterns and priority areas. To begin, a mind mapping exercise was conducted to visually group focus areas in neurotechnology-relevant and neurotechnology-specific policy initiatives as well as stakeholder inputs for the question on current key priorities or focus areas in relation to the development, regulation, or oversight of neurotechnology. This helped reveal interconnections across policy and participant responses. Building on this, a thematic analysis was performed to cluster recurring topics into broader categories, which informed the identification of key organizational dimensions essential for evaluating responsible innovation. These synthesized insights laid the groundwork for the development of a targeted conceptual framework in the next stage of the design process.

Mind mapping

Neurotechnology-relevant policy initiatives focus areas

The mind mapping exercise for neurotechnology-relevant policy initiatives revealed a range of interconnected focus areas that, while not specific to neurotechnology, significantly influence its development and regulation. Key themes that emerged included privacy and data protection, informed consent, human rights, research ethics,

innovation and inclusion, medical device safety, AI ethics, accessibility, and equity. These focus areas were often linked across multiple initiatives, illustrating the broad ethical and legal expectations shaping the environment in which neurotechnology operates. The mind map helped visualize how overlapping regulatory domains, such as healthcare, data governance, and artificial intelligence, contribute foundational principles that neurotechnology enterprises must navigate, despite the absence of targeted neurotechnology regulations in many cases.

Figure 8: Neurotechnology-relevant policy initiatives focus areas mind map

Neurotechnology-specific policy initiatives focus areas

The mind mapping of neurotechnology-specific policy initiatives highlighted focus areas that directly address the unique ethical, legal, and societal challenges posed by emerging neurotechnology. Central themes included mental privacy, cognitive liberty, personal identity, informed consent, safety, efficacy, regulatory pathways, and neural data protection. Unlike broader frameworks, these initiatives concentrated heavily on safeguarding the integrity of cognitive functions and protecting individuals' mental autonomy. The mind map also showed growing attention to consumer protection and cyberneurosecurity, particularly as non-clinical neurotechnology applications expand. This visual synthesis illustrated that while neurotechnology-specific policies are still

emerging, they prioritize distinct risks and rights that are not fully captured by traditional biomedical or data governance frameworks.

Figure 9: Neurotechnology-specific policy initiatives focus areas mind map

Stakeholders focus areas

The stakeholder focus area mind map in the image illustrates a wide range of priorities identified as critical to ensuring responsible innovation in neurotechnology. Central concerns include data protection, regulatory oversight, and cross-border compliance, reflecting the need for robust governance structures. Ethical and social considerations are prominent, such as informed consent, mental privacy, non-discrimination, and autonomy, highlighting the importance of protecting user rights. Stakeholders also stressed the need for equitable access, inclusion of vulnerable populations, and accessibility, ensuring that neurotechnology benefits are distributed fairly. Other key focus areas include AI accountability, risk mitigation, personal agency, cognitive freedom, and corporate social responsibility. Additionally, the map emphasizes public awareness, collaboration, and stakeholder enablement as essential strategies for building trust and transparency in neurotechnology policy and practice.

Figure 10: Stakeholder focus areas mind map

The stakeholder focus areas mind map illustrates a broad range of priorities that regulatory bodies, industry leaders, and advocates consider essential for promoting responsible neurotechnology innovation. Central concerns include data protection, regulatory oversight, cross-border compliance, and the establishment of clear safety standards. Ethical imperatives such as corporate social responsibility, inclusion of vulnerable populations, cognitive freedom, and personal agency were also strongly emphasized. Stakeholders highlighted the importance of public awareness, stakeholder enablement, and collaboration to ensure transparency, accessibility, and equitable access to neurotechnology. Additional focus areas included informed consent, mental privacy, non-discrimination, autonomy, artificial intelligence governance, and risk mitigation, reflecting a comprehensive view of the technical, ethical, and societal dimensions that must be addressed in emerging policies and practices.

Thematic analysis

Thematic analysis was conducted to systematically identify, organize, and interpret patterns within the data gathered from the environmental scan, stakeholder engagement, and mind mapping exercises. By coding key focus areas and grouping them into related categories, the analysis revealed recurring themes critical to

responsible neurotechnology innovation, including governance, data protection, technology development, and user-centered practices. This process allowed for a structured understanding of complex insights, ensuring that the emerging framework and evaluation tool directly addressed the most significant ethical, legal, and operational needs identified across different sources. Thematic analysis thus served as a foundational step in transforming scattered findings into actionable design directions.

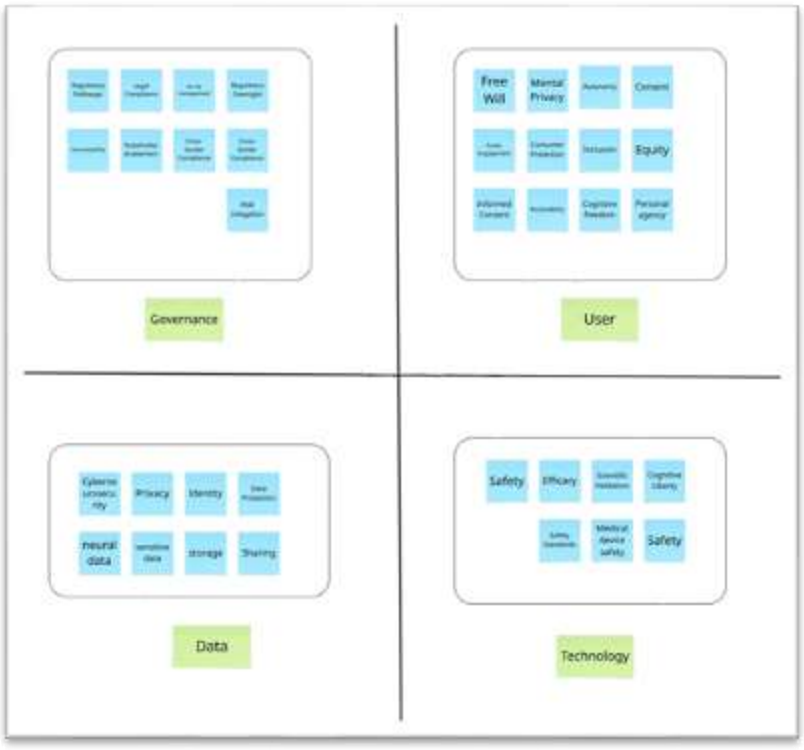

Figure 11: Thematic analysis

Development of conceptual framework

Following the thematic analysis, four key organizational dimensions were identified as central to evaluating responsible innovation in neurotechnology enterprises: **Governance**, **Data**, **Technology**, and **User**. Governance refers to the structures, policies, and accountability mechanisms that guide ethical decision-making and regulatory compliance within the organization. Data focuses on the responsible management, protection, and ethical use of sensitive neural and personal data across its lifecycle. Technology encompasses the development, deployment, and continuous

improvement of neurotechnology products, ensuring they meet standards of safety, efficacy, and fairness. User addresses the rights, experiences, and ongoing support of individuals interacting with neurotechnology, emphasizing autonomy, informed consent, and equitable access. Together, these four dimensions form the foundation of the conceptual framework, ensuring a comprehensive and actionable approach to assessing responsible innovation practices. The conceptual framework developed through this project is titled the Responsible Neurotechnology Framework (RNF).

Figure 12: Responsible Neurotechnology Framework (RNF)

Building on the conceptual framework comprising the four key dimensions - Governance, Data, Technology, and User - the next step was to translate these thematic insights into a tangible design outcome. The framework revealed critical areas where responsible innovation must be embedded and evaluated within neurotechnology enterprises. However, while the framework outlined *what* to assess, it did not yet offer a method for *how* to assess it in practice. This led to the central design challenge.

Design challenge

How might we develop an evaluation tool that helps regulatory bodies assess the status of responsible innovation in neurotechnology enterprises?

Design criteria and success indicators

To ensure the evaluation tool meets its intended purpose, several design criteria were established. The tool must be clear and easy to use, allowing regulatory bodies to efficiently assess neurotechnology enterprises without requiring extensive training. It must be aligned with the four framework dimensions - Governance, Data, Technology, and User - providing structured yet flexible guidance that accommodates evolving policy contexts. Additionally, it must be adaptable across jurisdictions, recognizing differences in regulatory maturity and scope. Success indicators for the tool include positive expert validation, alignment with existing policy goals, and its perceived usefulness by regulatory stakeholders in identifying areas for improvement and accountability within neurotechnology enterprises.

To conclude, the second phase translated the rich insights gathered during first phase into a structured foundation for design. Through mind mapping, thematic analysis, and the identification of four key a conceptual framework was developed to represent the core areas of responsible neurotechnology innovation. This framework informed the articulation of a focused design challenge aimed at creating an evaluation tool that enables regulatory bodies to assess the position of neurotechnology enterprises in implementing responsible practices. With clear design criteria and success indicators established, the project moved into the third phase to prototype and refine this solution.

Chapter 4 – Designing Responsible Neurotechnology Evaluation Tool (RNET)

The third phase focused on generating, prototyping, and refining solutions based on the conceptual framework and design challenge established during the second phase. This stage involved translating the identified dimensions and priorities into a practical evaluation tool that regulatory bodies could use to assess responsible innovation practices in neurotechnology enterprises. Early concepts were shaped through ideation, followed by the development of initial prototypes, expert feedback, and iterative refinement to ensure the tool was both relevant and functional within a dynamic policy and technological landscape.

Ideation and early concepts

With the problem space clearly defined and the Responsible Neurotechnology Framework (RNF) established, the project moved into the ideation phase to explore possible solutions. Brainstorming sessions focused on how the framework could be operationalized into a practical tool for regulatory use. Key ideas included a checklist-based evaluation form, a scoring matrix, and a progress-mapping system aligned with the four dimensions of the RNF – Governance, Data, Technology, and User. These early concepts aimed to balance clarity, usability, and flexibility. The ideation process laid the groundwork for developing a functional prototype that could support evidence-based evaluation and regulatory decision-making in the neurotechnology space.

The concept that was selected after the brain-storming session was a checklist-based evaluation form designed to help regulatory bodies systematically assess responsible innovation practices within neurotechnology enterprises. This format was chosen for its simplicity and familiarity, offering a structured way to review compliance across the four dimensions of the Responsible Neurotechnology Framework (RNF). Each item on the checklist corresponded to a specific proof point, allowing evaluators to quickly verify whether essential governance, data, technology, and user-related practices were in place.

Prototype 1

The first iteration of the evaluation tool, Prototype 1, was developed as a checklist-based model structured around the four key dimensions of the Responsible Neurotechnology Framework (RNF): Governance, User, Data, and Technology. Under each dimension, specific proof points were identified to represent concrete organizational actions that support responsible innovation. These proof points are broader policy actions or evidence of linking organizational practices to regulatory goals by the neurotechnology enterprises. Evaluators could use the checklist to verify whether each proof point was addressed within an enterprise, providing a straightforward, itemized assessment.

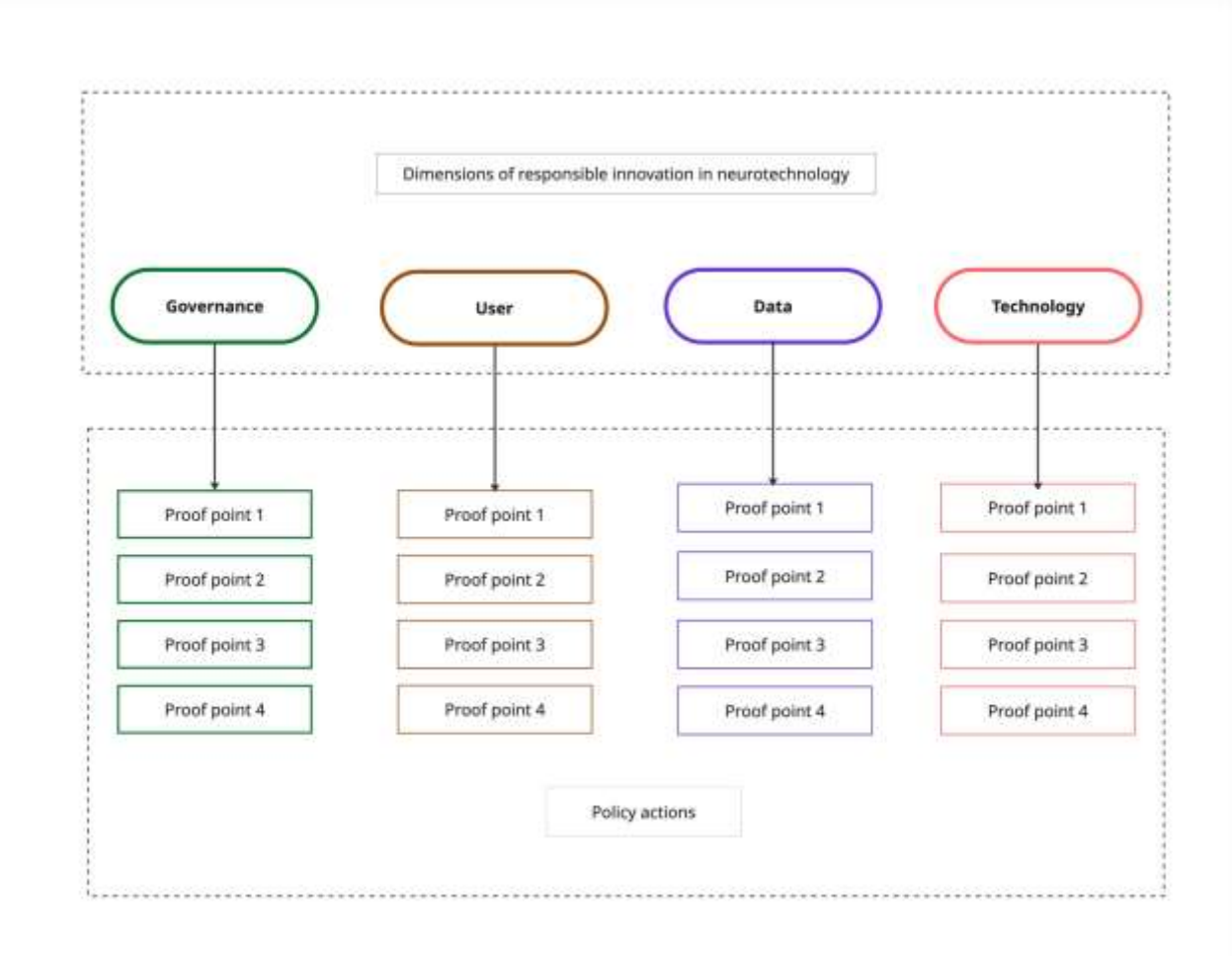

Figure 13: First iteration of evaluation tool

Feedback from subject matter experts

While effective in identifying the presence or absence of specific elements, the checklist format revealed limitations in capturing the depth and maturity of organizational efforts, which informed later refinements in the tool's design. Subject matter experts appreciated the clarity and structure of the first prototype, particularly its alignment with the four dimensions of responsible innovation - Governance, Data, Technology, and User. They found the checklist format useful for identifying whether essential organizational practices were in place, making it accessible for both regulatory and organizational use. However, experts noted that the binary nature of the checklist limited its ability to reflect the depth, maturity, or progress of those practices over time. They emphasized the need for a more nuanced evaluation model that could capture varying levels of implementation and organizational commitment.

Prototype 2

In response to expert feedback on the first iteration, Prototype 2 was developed to move beyond a binary checklist and introduce a more dynamic evaluation approach. Experts emphasized the need for a tool that not only identifies whether responsible innovation practices are in place but also captures the depth and maturity of their implementation. Specifically, they recommended that the tool support both point-in-time assessment and longitudinal tracking to reflect organizational progress over time. This led to the incorporation of a stage-based evaluation model, allowing assessors to assign levels of progress to each proof point within the four framework dimensions - providing a more comprehensive and actionable view of responsible innovation maturity.

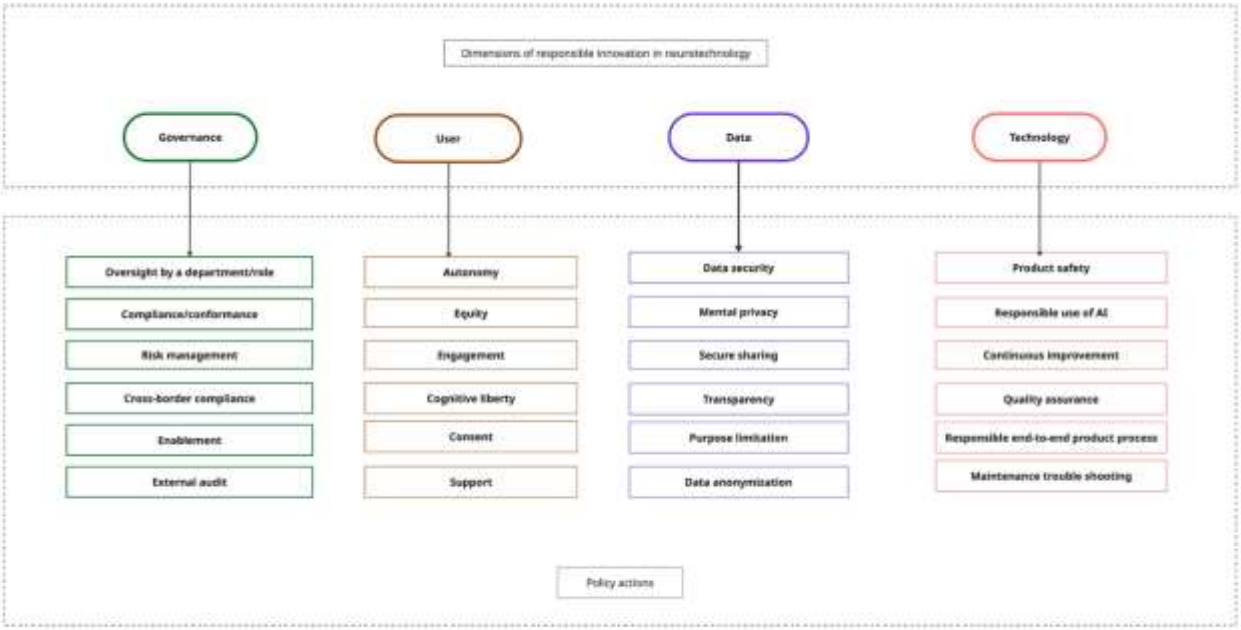

Figure 14: Proof points for RNF dimensions

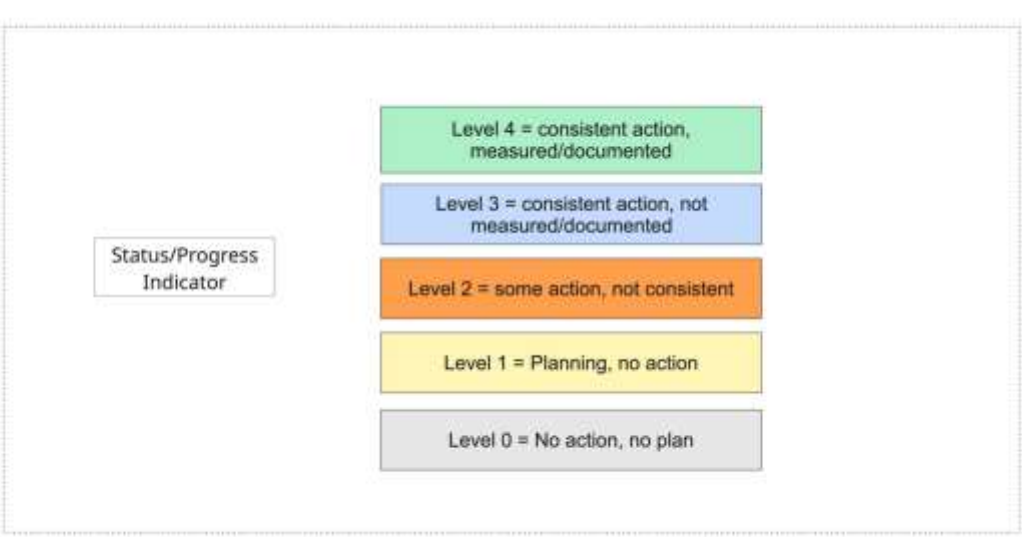

Figure 15: Status/progress indicator

The proof points for each dimension were determined through stakeholder insights and continuous feedback. For example, under Governance, items such as risk management, cross-border compliance, and oversight by a designated role guide

evaluators to examine structural and accountability measures. The User dimension includes items like autonomy, informed consent, and cognitive liberty, emphasizing ethical engagement and rights. The Data dimension covers areas such as data security, purpose limitation, and mental privacy, while the Technology dimension highlights critical aspects such as product safety, continuous improvement, and responsible AI use.

After adding the relevant proof points for the four dimensions, five-level status/progress indicator **u**sed to evaluate the maturity of responsible innovation practices across each proof point in the framework. The scale ranges from Level 0 to Level 4**,** enabling evaluators to assess not just the presence of action but also its consistency, measurement, and documentation.

- **Level 0** indicates *no action and no plan*.
- **Level 1** indicates *planning in place, but no action taken*.
- **Level 2** indicates *some action, but inconsistently applied*.
- **Level 3** is for *consistent action that is not formally measured or documented*.
- **Level 4** is for *consistent, measured, and well-documented action*, indicating the highest level of maturity.

This layered approach supports both point-in-time assessments and longitudinal tracking, helping regulatory bodies understand not only whether responsible practices exist but how robust and sustainable they are in a neurotechnology enterprise.

Responsible Neurotechnology Evaluation Tool (RNET)

Before presenting the final version of the Responsible Neurotechnology Evaluation Tool (RNET), a collaborative and iterative approach was taken to ensure that the prototype aligned with real-world regulatory needs. Multiple engagement sessions were conducted with regulators and subject matter experts in neurotechnology policy to gather insights on usability, clarity, and relevance. Additional feedback was collected asynchronously through email communication and usability testing, providing valuable input on the tool’s structure and user experience. These findings were incorporated into

the final design of RNET, which has been developed as a web-based form to enable structured, accessible, and scalable evaluations of responsible innovation practices across neurotechnology enterprises. In the final version of the tool, several proof point statements were refined for clarity, consistency, and ease of interpretation based on feedback from regulators and subject matter experts.

In the final version, each proof point is elaborated as a clear, descriptive statement to help organizations better understand the expectations and assess their practices with greater clarity and consistency.

The ‘governance’ dimension consists of the following proof point statements:

- The organization has a specific department/role that oversees responsible innovation across products, functions, processes, and organizational practices.
- Mechanisms are in place to ensure conformance with applicable global and regional standards and guidelines for responsible neurotechnology innovation
- Mechanisms are in place to identify potential risks, evaluate their impact, and implement strategies to manage risks related to neurotechnology
- Prioritizes national security considerations and maintains compliance with applicable cross-border regulatory requirements
- Role-specific training on responsible innovation is provided for all relevant stakeholders
- Third-party audits to verify product compliance with the necessary standards

The ‘user’ dimension has the following proof point statements:

- The organization ensures that users are provided with the necessary information and autonomy to make independent decisions and maintain control over their neurotechnology interactions
- Fair treatment and equitable access to neurotechnology are ensured for all users, with specific attention to addressing diverse needs and circumstances

- The organization actively engages users throughout the product development and usage lifecycle, encouraging participation, collaboration, and feedback to enhance responsible innovation practices
- The organization implements measures to safeguard users' cognitive freedom, preserving individuals' autonomy over their mental and cognitive functions in all neurotechnology interactions
- Informed consent is obtained from users prior to engagement with neurotechnology, supported by transparent communication of potential risks and benefits
- The organization ensures that users have ongoing access to necessary resources, support services, and timely updates throughout their engagement with the technology

The ‘data’ dimension has the following proof point statements:

- Measures are implemented to protect sensitive data from unauthorized access, breaches, and other security threats
- Mechanisms are in place to protect individuals' mental privacy by ensuring that neural data remains confidential and is used only with explicit, informed consent
- Secure data-sharing practices are implemented, ensuring that encryption and authorization protocols are consistently applied to protect data integrity and confidentiality
- The organization ensures transparency in data handling by clearly communicating practices related to data collection, usage, storage, and protection to all stakeholders
- Guidelines are established for storing and using data, ensuring it is securely maintained and used solely for its intended purposes
- Robust techniques are employed to safeguard individuals' identities during data use for research or analysis, preserving privacy and minimizing the risk of re-identification

The proof point statements for ‘technology’ dimension are as follows:

- Established safety standards are in place to protect users from potential harm associated with the development and use of neurotechnology
- AI systems are developed and deployed in an equitable and responsible manner, prioritizing fairness, transparency, and inclusivity in all AI-driven processes
- The organization continuously enhances its technology capabilities by integrating user feedback, aligning with regulatory updates, and adopting emerging best practices
- Quality control processes are established to ensure that all products consistently meet high standards of reliability and performance
- The organization embeds responsible innovation principles across all stages of the neurotechnology development lifecycle, from design and testing to deployment and post-market monitoring
- The organization delivers continuous user support, including timely product updates, maintenance services, and responsive assistance to address user needs

To support easy reference, a detailed table of the four dimensions and proof points of RNET is provided in tabular format in the Appendix 2.

The third phase transformed the conceptual framework into a practical and actionable evaluation tool tailored to the needs of regulatory bodies overseeing neurotechnology innovation. Through iterative prototyping, expert feedback, and usability testing, the tool evolved from a simple checklist to a structured, maturity-based assessment model that captures both point-in-time status and organizational progress over time. Key refinements, including the introduction of a progress indicator and the development of a web-based form, ensured that the final version of the Responsible Neurotechnology Evaluation Tool (RNET) is both accessible and aligned with responsible innovation goals and regulatory priorities. With a robust structure grounded in real-world needs, the project now moves to the final phase of presenting and reflecting on the outcomes.

Chapter 5 – Iterative Development of RNET

The fourth phase marks the transition from iterative development to the finalization and validation of the Responsible Neurotechnology Evaluation Tool (RNET). This stage focused on incorporating expert feedback, refining the tool's structure and content, and ensuring alignment with the project's research objectives and framework dimensions. The final version of RNET was developed as a web-based form designed for practical use by regulatory bodies, with features that support both point-in-time assessment and longitudinal tracking. This chapter outlines the final tool's structure, highlights key improvements made from earlier prototypes, and presents its alignment with ethical standards and international policy principles, including the OECD's recommendations and Canada's adapted five guiding principles for responsible neurotechnology innovation.

Finalization of RNET

The final version of the Responsible Neurotechnology Evaluation Tool (RNET) was developed as a web-based form to support practical, accessible, and consistent evaluation of responsible innovation practices across neurotechnology enterprises.

The final version is accessible via the following web form:

Responsible Innovation Evaluation Tool (RNET)

To support easy reference, a detailed table of the four dimensions and proof points of RNET is provided in tabular format in the Appendix 2.

Threshold-based allocation determines the final level of a neurotechnology enterprise within the evaluation tool. By setting predetermined thresholds for each dimension, the approach ensures that an enterprise cannot achieve a higher overall level if it falls short in any critical area. For example, if an enterprise's performance in the governance or data dimension is assessed at a lower level (e.g., Level 2), it would automatically limit the overall progress rating, regardless of performance in other areas. This approach

emphasizes the importance of achieving a minimum standard of responsible innovation across all dimensions, ensuring that enterprises cannot be rated highly without adequately addressing essential aspects such as safety, privacy, and inclusivity. By incorporating this method, the evaluation tool guarantees that the neurotechnology enterprise meets essential criteria for responsible innovation in a balanced manner.

Validation against project goals

The Responsible Neurotechnology Evaluation Tool (RNET) was developed to align closely with the overarching goals of responsible innovation by bridging the gap between high-level ethical standards and practical organizational practices. It provides regulatory bodies with a structured mechanism to assess whether neurotechnology enterprises are embedding responsible practices across governance, data management, technology development, and user support. The tool reflects the evolving policy landscape, international best practices, and guidelines.

The fourth phase marked the successful completion and validation of the Responsible Neurotechnology Evaluation Tool (RNET), resulting in a practical, web-based solution tailored for regulatory use. Through expert feedback, iterative refinement, and usability enhancements, the final tool supports both point-in-time assessment and ongoing progress tracking across four key dimensions: Governance, User, Data, and Technology. Each proof point is presented as a clear, actionable statement, enabling organizations to understand and evaluate their responsible innovation practices with confidence. Importantly, the proof points embedded within RNET are aligned with the OECD principles for responsible innovation in neurotechnology as well as the refined five principles developed for the Canadian context, ensuring the tool reflects internationally recognized policy initiative. With its structured format and real-world applicability, RNET is positioned to support regulatory oversight and guide enterprises toward more accountable and inclusive neurotechnology innovation.

Chapter 6 – Conclusion

Anchored in an iterative design approach, the project aimed to address a critical gap in the responsible innovation landscape by developing a practical evaluation tool tailored for regulatory oversight in the neurotechnology sector. Through a iterative design process, the Responsible Neurotechnology Evaluation Tool (RNET) emerged as a meaningful response to the challenge of translating high-level ethical principles into actionable organizational practices. This chapter summarizes the project's impact, discusses areas for improvement, and outlines recommendations for future development and broader application.

Project Contributions to Inclusive Design Practice

This project contributes to the practice of inclusive design by extending its application from product-level accessibility to the broader context of organizational responsibility and regulatory evaluation in the neurotechnology sector. It demonstrates how inclusive design can inform the governance of emerging technologies, ensuring that innovation is not only accessible but also ethically grounded, user-centered, and socially accountable.

By introducing the Responsible Neurotechnology Framework (RNF) and the accompanying Responsible Neurotechnology Evaluation Tool (RNET), the project offers practical mechanisms for regulatory bodies and neurotech enterprises to assess whether responsible inclusion is embedded in organizational practices. These tools shift the focus from reactive accommodation to proactive, evidence-based decision-making that centers the rights, needs, and safety of people who are most likely to be affected or excluded.

The project also reinforces the virtuous tornado model of inclusive design, where co-design is central and continuous. While the initial development and implementation of the tool were guided by expert input, the need for ongoing evaluation and refinement reflects the iterative, participatory spirit of inclusive design. Testing these tools within real-world regulatory environments will further ground them in practice and ensure their adaptability to diverse organizational contexts.

Ultimately, this project advances inclusive design practice by emphasizing that inclusion alone is not sufficient—it focuses on responsible inclusion, ensuring that individuals at the margins, including those in high-risk or edge-case scenarios, are not only included but protected from potential harm. By embedding ethical safeguards and inclusive values into the evaluation of organizational practices, the project moves beyond traditional notions of accessibility.

Limitations

Since neurotechnology is a rapidly evolving field, emerging innovations, risks and policy responses may shift during or after the completion of this study. The framework developed is conceptual or early-stage in nature. This framework is informed by expert insights but may require further testing and refinement before practical implementation. The field of neurotechnology is still in its nascent stages, resulting in a limited number of experts with deep experience. This limitation has implications for the breadth of expert insights; and the data points are illustrative rather than exhaustive. Due to the emerging neurotech applications, ongoing technological advancements, evolving landscape of policies, regulatory changes, compliance requirements, and governance structures the proposed framework and accompanying evaluation tool may require iterative updates over time to remain relevant and effective.

Recommendations for Future Development

- Pilot the tool with regulatory bodies, such as Health Canada, to validate usability, relevance, and impact in real-world regulatory settings and to decide the frequency of evaluation.
- Develop an advanced-level maturity model that covers the entire neurotechnology lifecycle, from research and development through deployment and post-market monitoring.
- Expand engagement by involving end-users, neurotechnology developers, and other stakeholder groups to refine proof points, ensure broader applicability, and strengthen trust in the evaluation process.

- Develop complementary evaluation tools tailored for organizations that utilize neurotechnology as part of their services but are not directly involved in product development, to ensure responsible use across different industry settings.

Final reflections

This project has demonstrated the value of applying human-centered, inclusive design methods to complex ethical and regulatory challenges in emerging technologies. The development of RNET reflects a shift from abstract ethical discourse to grounded, operational tools that can support responsible innovation in real-world contexts. Personally, the process reinforced the importance of cross-disciplinary collaboration, iterative prototyping, and responsive feedback in shaping meaningful policy tools. As neurotechnology continues to evolve, tools like RNET can play a crucial role in fostering transparency, accountability, and equity - ensuring that innovation aligns with the broader values of society.

References

Accessibility Standards Canada. (2025). *Accessible and Equitable Artificial Intelligence Systems (CAN-ASC-6.2)*. https://accessible.canada.ca/creating-accessibility-standards/asc-62-accessible-equitable-artificial-intelligence-systems

Beauchamp, T.L., and J.F. Childress. 2013. Principles of biomedical ethics. 7th ed. New York: Oxford University Press.

California Department of Justice. (2025). California Consumer Privacy Act (CCPA). Office of the Attorney General. https://oag.ca.gov/privacy/ccpa

Cassin, R. (2024, March 21). *California amends key CCPA definitions: AB 947 and AB 1194 highlight growing regulation of sensitive and biometric information*. The National Law Review. https://natlawreview.com/article/california-amends-key-ccpa-definitions#:~:text=Assembly%20Bill%20(AB%201008)%20and,biometric%20information%20among%20the%20states

Canadian Biotechnology Action Network. (n.d.). Precautionary principle. https://cban.ca/about-us/priorities/democracy-and-government-regulation/precautionary-principle/#:~:text=%E2%80%9C%20When%20it%20comes%20to%20human,of%20evidence%20is%20not%20enough.%E2%80%9D

Canadian Brain Research Strategy. (n.d.). The challenge: Understanding the brain. https://canadianbrain.ca

Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, & Social Sciences and Humanities Research Council of Canada. (2018). *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)*. https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html

Colorado General Assembly. (2024). *House Bill 24-1058: Consumer protections for neural data*. https://leg.colorado.gov/bills/hb24-1058

Council of Europe. (1997). Convention on Human Rights and Biomedicine (Oviedo Convention). https://www.coe.int/en/web/human-rights-and-biomedicine/oviedo-convention

Demos Helsinki (2022). What is the Collingridge dilemma in tech policy? https://demoshelsinki.fi/what-is-the-collingridge-dilemma-tech-policy/

European Union. (2016). *Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation)*. Official Journal of the European Union, L119, 1–88. https://eur-lex.europa.eu/eli/reg/2016/679/oj

European Union. (2017). *Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Medical Device Regulation)*. Official Journal of the European Union, L117, 1–175. https://eur-lex.europa.eu/eli/reg/2017/745/oj

European Union. (2024). *Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending certain Union legislative acts (Artificial Intelligence Act)*. *Official Journal of the European Union*, L 2024/1689, 12 July 2024. https://eur-lex.europa.eu/eli/reg/2024/1689/oj

Farhany, N. (2023). The battle for your brain: Defending the right to think freely in the age of neurotechnology. St. Martin's Press. https://us.macmillan.com/books/9781250272966/thebattleforyourbrain/

Government of Canada. (2004). *Personal Information Protection and Electronic Documents Act (S.C. 2000, c. 5)*. https://laws-lois.justice.gc.ca/eng/acts/p-8.6/

Global Burden of Disease Collaborative Network. (2020). Global burden of disease study 2019 (GBD 2019) disease and injury burden 1990-2019. Institute for Health Metrics and Evaluation. https://doi.org/10.6069/GBD-CITATION

Ienca, M. (2021). Common human rights challenges raised by different applications of neurotechnologies in the biomedical fields. Committee of Bioethics of the Council of Europe. https://www.coe.int/en/web/bioethics/neurotechnology

Ienca, M., & Andorno, R. (2017). Towards a neurorights framework: Genetic data, cognitive liberty, and the right to mental privacy. The American Journal of Bioethics, 17(7), 42-52. https://doi.org/10.1080/15265161.2017.1322975

Illes J, Boehnke S, Chandler JA, et al. Principles and Priorities for Responsible Innovation in Neurotechnology for Canada. *Canadian Journal of Neurological Sciences / Journal Canadien des Sciences Neurologiques*. Published online 2024:1-4. doi:10.1017/cjn.2024.322

Inclusive Design Research Centre. (n.d.). *Philosophy*. OCAD University. https://idrc.ocadu.ca/about/philosophy/

Institute of Electrical and Electronics Engineers. (2020). *IEEE Code of Ethics*. https://www.ieee.org/about/corporate/governance/p7-8.html

Institute of Electrical and Electronics Engineers. (2022). Neurotechnologies: The next technology frontier. IEEE Brain. https://brain.ieee.org/topics/neurotechnologies-the-next-technology-frontier/

Kandel, E. R., Schwartz, J. H., & Jessell, T. M. (2000). *Principles of neural science* (4th ed.). McGraw-Hill, Health Professions Division

Mexican Senate. (2024, July 17). *General Law on Neuro-Rights and Neurotechnologies*. https://digitalpolicyalert.org/change/10500

Minnesota Legislature. (2023). *House File 1904: Neurodata protection and neurorights* (HF 1904, 93rd Legislature). https://www.revisor.mn.gov/bills/text.php?number=HF1904&version=0&session=ls93&session_year=2023&session_number=0

National Institutes of Health, BRAIN Initiative. (2018, March 6). *Neuroethics guiding principles for the NIH BRAIN Initiative*. https://braininitiative.nih.gov/news-events/blog/neuroethics-guiding-principles-nih-brain-initiative

NeuroRights Foundation. (n.d.). *NeuroRights Foundation*. https://neurorightsfoundation.org/

NeuroRights Foundation. (2021, October 25). Chile passes constitutional reform to protect neuro-rights. https://neurorightsfoundation.org/chile#:~:text=October%2025th%2C%202021%3A%20The%20Chilean,the%20senate%20was%20concurrently%20established

Neurotech Guidebook Development Committee. (2024). *Neurotech guidebook vol.2: For responsible development by enterprise*. Araya Inc. https://www.araya.org/en/publications/news20240717/

Organization for Economic Co-operation and Development (OECD). (2019). OECD recommendations on responsible innovation in neurotechnology. OECD Publishing. https://doi.org/10.1787/5jrs1w41bfvh-en

OECD. (2025). OECD legal instruments: OECD legal instrument on responsible innovation in neurotechnology. Organisation for Economic Co-operation and Development. https://legalinstruments.oecd.org/en/instruments/oecd-legal-0457

Republic of Chile. (2021). *Reforma Constitucional: Incorpora los neuroderechosy la protección de la integridad mental en la Constitución Política de la República de Chile* [Constitutional Reform: Incorporates neuro-rights and the protection of mental integrity

into the Political Constitution of the Republic of Chile]. https://www.bcn.cl/leychile/navegar?idNorma=1159829

Stieglitz, T. (2021) Why Neurotechnologies? About the Purposes, Opportunities and Limitations of Neurotechnologies in Clinical Applications. Neuroethics 14, 5–16. https://doi.org/10.1007/s12152-019-09406-7

Stiljoie, J., Owen, R., & Macnaghten, P. (2013). Developing a framework for responsible innovation. Research Policy, 42(9), 1568-1580. https://doi.org/10.1016/j.respol.2013.05.008

Treviranus, J. (n.d.). Inclusive design: The bell curve, the starburst, and the virtuous tornado. Medium. https://medium.com/@jutta.trevira/inclusive-design-the-bell-curve-the-starburst-and-the-virtuous-tornado-6094f797b1bf

UNESCO. (2005). Universal Declaration on Bioethics and Human Rights. https://www.unesco.org/en/ethics-science-technology/bioethics-and-human-rights

UNESCO (2023). Ethics of neurotechnology. United Nations Educational, Scientific and Cultural Organization. https://www.unesco.org/en/ethics-neurotech

UNESCO. (2024). *Recommendation on the ethics of neurotechnology*. https://unesdoc.unesco.org/ark:/48223/pf0000393395

UNESCO. (2023, February 13). UNESCO to lead global dialogue on the ethics of neurotechnology. UNESCO. https://www.unesco.org/en/articles/unesco-lead-global-dialogue-ethics-neurotechnology

UNESCO. (n.d.). Ethics of neurotechnology. https://www.unesco.org/en/ethics-neurotech

U.S. Department of Health and Human Services. (1996). Health Insurance Portability and Accountability Act of 1996 (HIPAA). Office of the Assistant Secretary for

Planning and Evaluation. https://aspe.hhs.gov/reports/health-insurance-portability-accountability-act-1996

U.S. Food and Drug Administration. (2011). *Premarket approval (PMA)*. https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma

U.S. Food and Drug Administration. (2018). *Brain-computer interface (BCI) devices for patients with paralysis or amputation: Summary report*. U.S. Department of Health and Human Services. https://www.fda.gov/media/120362/download

World Health Organization. (2021). *Ethics and governance of artificial intelligence for health: WHO guidance*. https://www.who.int/publications/i/item/9789240029200

Appendix 1 – Timeline of neurotechnology policy initiatives

Appendix 2 – RNET dimensions and proof points

No.	Dimensions and proof points	Level (0 to 4)
A	***Governance***	
A1	The organization has a specific department/role that oversees responsible innovation across products, functions, processes, and organizational practices	
A2	Mechanisms are in place to ensure conformance with applicable global and regional standards and guidelines for responsible neurotechnology innovation	
A3	Mechanisms are in place to identify potential risks, evaluate their impact, and implement strategies to manage risks related to neurotechnology	
A4	Prioritizes national security considerations and maintains compliance with applicable cross-border regulatory requirements	
A5	Role-specific training on responsible innovation is provided for all relevant stakeholders	
A6	Third-party audits to verify product compliance with the necessary standards	
B	***User***	
B1	The organization ensures that users are provided with the necessary information and autonomy to make independent decisions and maintain control over their neurotechnology interactions	
B2	Fair treatment and equitable access to neurotechnology are ensured for all users, with specific attention to addressing diverse needs and circumstances	
B3	The organization actively engages users throughout the product development and usage lifecycle, encouraging	

	participation, collaboration, and feedback to enhance responsible innovation practices	
B4	The organization implements measures to safeguard users' cognitive freedom, preserving individuals' autonomy over their mental and cognitive functions in all neurotechnology interactions	
B5	Informed consent is obtained from users prior to engagement with neurotechnology, supported by transparent communication of potential risks and benefits	
B6	The organization ensures that users have ongoing access to necessary resources, support services, and timely updates throughout their engagement with the technology	
C	***Data***	
C1	Measures are implemented to protect sensitive data from unauthorized access, breaches, and other security threats	
C2	Mechanisms are in place to protect individuals' mental privacy by ensuring that neural data remains confidential and is used only with explicit, informed consent	
C3	Secure data-sharing practices are implemented, ensuring that encryption and authorization protocols are consistently applied to protect data integrity and confidentiality	
C4	The organization ensures transparency in data handling by clearly communicating practices related to data collection, usage, storage, and protection to all stakeholders	
C5	Guidelines are established for storing and using data, ensuring it is securely maintained and used solely for its intended purposes	
C6	Robust techniques are employed to safeguard individuals' identities during data use for research or analysis, preserving privacy and minimizing the risk of re-identification	

D	***Technology***	
D1	Established safety standards are in place to protect users from potential harm associated with the development and use of neurotechnology	
D2	AI systems are developed and deployed in an equitable and responsible manner, prioritizing fairness, transparency, and inclusivity in all AI-driven processes	
D3	The organization continuously enhances its technology capabilities by integrating user feedback, aligning with regulatory updates, and adopting emerging best practices	
D4	Quality control processes are established to ensure that all products consistently meet high standards of reliability and performance	
D5	The organization embeds responsible innovation principles across all stages of the neurotechnology development lifecycle, from design and testing to deployment and post-market monitoring	
D6	The organization delivers continuous user support, including timely product updates, maintenance services, and responsive assistance to address user needs	